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FDA Enforcement Report

Press Office
Food and Drug Administration
5600 Fishers Lane
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The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

PROSECUTION: A criminal action filed by FDA against a company or individual charging violation of the law. Prosecutions listed below have been filed with a court but not yet tried or concluded.

SEIZURE: An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods until the matter is recolved. The date listed is the date a seizure request is filed, not the date of seizure.

INJUNCTION: A civil action filed by FDA against an individual or company seeking, in most cases, to stop a company from continuing to manufacture or distribute products that are in violation of the law. Injunctions listed have been filed with the court but not concluded.

RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

January 6, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Staff Crunchy Peanut Butter, net weight 18 ounces, Recall #F-043-2
Code:	"SELL BY JUL 1 1982 J" stamped on jar lid
Manufacturer:	Sunnyland Refining Company, Inc., Birmingham, Alabama
Recalled by:	Manufacturer, by letter, October 2, 1981. Firm initiated recall complete
Distribution:	Ohio
Size & Quantity:	Firm estimates none remains on market
Reason:	The product contains aflatoxin.

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Product: Dextrostix Brand Reagent Strips, product is a one-minute test for glucose in whole blood, for in-vitro diagnostic use, packaged in 25 strip bottle, Recall #T-052-2
Code: Control #'s (a) 0007100 - exp. date Oct. 1982, (b) 0008100 - exp. date Oct. 1982, (c) 0009110 - exp. date Nov. 1982, (d) 5009110 - exp. date Nov. 1982, (e) 0012110 - exp. date Nov. 1982, (f) 0016110 exp. date Nov. 1982, (g) 0033110 - exp. date Nov. 1982
Manufacturer: Ames Co., Div. of Miles Labs Inc., Elkhart, Indiana
Recalled by: Manufacturer, by recall letters, week of November 30 - December 4, 1981. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 147,657 bottles of 25 strips were distributed. Firm estimates less than 10% remains on market.
Reason: The reagent strips may give false low blood glucose test results.

Product: Tridilset tm, a special nonabsorbing I.V. Administration Set. Tridilset is not sold separately, but is packaged w/Tridil tm I.V. Nitroglycerin Preparation (5 mg./ml.), Recall #T-055-2
Code: All lots
Manufacturer: (a) Tridilset: McGaw Labs, Inc., Sabana Grande, Puerto Rico
(b) Tridil: Arnar Stone Del Caribe, Inc., Aguadilla, Puerto Rico
Recalled by: American Critical Care, Division of American Hospital Supply Corp., McGaw Park, Illinois, by means of a field correction via letter dated November 19, 1981 in which appropriate warnings for use were detailed. Subsequent package shipped contained these warnings. The firm is adding appropriate warnings to the package labeling and is not requesting returns of product. Firm initiated action.
Distributed: Nationwide
Size & Quantity: Approximately 50,000 units distributed
Reason: A potential safety problem exists with the combined use of the IVAC Model 530 Infusion Pump and the Tridilset. The Tridilset is less pliable than conventional PVC tubing such that the infusion pump may fail to occlude the Tridilset completely, which could lead to overinfusion of Tridil. Tridil (I.V. Nitroglycerin) is not a subject of this recall action.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: El Molino Brand All Natural Cookies in two ounce packages, all varieties, Recall #F-042-2
Code: All codes
Manufacturer: Southern Food Products, Vernon, California
Recalled by: Safeway Stores, Denver, Colorado, by inter-office memo, October 15, 1981. Firm initiated recall complete
Distribution: Rocky Mountain area
Size & Quantity: Unknown
Reason: Product was contaminated with Indian Meal Moth larva.

Product: Mini Stim Transcutaneous Electrical Nerve Stimulator- Control Unit, Recall #T-049-2
Code: Serial numbers 10001 thru 10033
Manufacturer: Medical Designs, Inc., Canton, Ohio
Recalled by: Manufacturer, by telephone, starting April 1, 1981. Firm initiated recall completed.
Distribution: Ohio
Size & Quantity: 33 units were distributed
Reason: Electrode wires become disengaged due to weakening of the jack and unit would not function.

Product: CRP-Wellcotest Rapid Latex Test Kit for Detection of C-Reactive Protein, an in-vitro diagnostic product, Recall #T-051-2
Code: Lot #K9869, EXP date 5/31/81
Manufacturer: Wellcome Reagents Limited, Beckenham, England
Recalled by: Burroughs Wellcome Company, Research Triangle Park, North Carolina, by issuing correction notices dated March 27, 1981. Firm initiated recall completed
Distribution: Nationwide
Size & Quantity: 247 kits were distributed
Reason: False negative results could be obtained when undiluted test specimens are used due to prozoning effect.

Seizure Actions Filed:

Product: Macaroni (81-261-433)
Charge: Product is contaminated with insect filth and has been held under insanitary conditions
Firm: Antone's Imports, Houston, Texas
Filed: December 3, 1981 - U.S. District Court for the Southern District of Texas at Houston; Civil #H-81-3170, FDC #63567.

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

January 13, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product: Digoxin Riabead Diagnostic Kit, a radioimmunoassay in-vitro diagnostic for the quantitative determination of serum digoxin concentration, 100 test units per kit box, Recall #T-044-2
Code: List No. 3088, kit lot #34-917-HC and 34-932-HC
Manufacturer: Abbott Laboratories, Diagnostic Division, North Chicago, Illinois
Recalled by: Manufacturer, by telephone and follow-up mailgram on November 7, 1981. Firm initiated recall completed
Distribution: Nationwide, Puerto Rico, Canada, Australia, Japan, New Zealand West Germany
Size & Quantity: Firm estimates none remains on market
Reason: The 2 ng/ml standard in the kit may contain incorrect concentrations of digoxin, which can result in erroneous quantitation of patient serum values. If test reads low, dosage to patient may be increased causing undue toxicity. If falsely high, patient may be deprived of needed medication.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

HE 20. 4032.

Product: Rubelisa Test Kit, product contains components necessary to perform enzyme-linked immunosorbent assay for rubella virus IgG antibody in patient serum, Recall #T-057-2
Code: Lot #40249
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by letter, January 29, 1981. Firm initiated recall completed
Distribution: Atlanta, Georgia and international
Size & Quantity: Firm estimates none remains on market
Reason: Moisture, as a result of desiccant failure, has reduced the reactivity of the plate.

Product: Fetal Bovine Serum in 500 ml glass units, an animal sera used for cell culturing, Recall #T-058-2
Code: Lot #98853
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by letter, April 2, 1981. Firm initiated recall completed
Distribution: Ohio, Minnesota, Maryland, New Jersey, Tennessee, New York, Denmark
Size & Quantity: Firm estimates none remains on market
Reason: Product may be contaminated with Mycoplasma arginini.

Product: Fetal Bovine Serum packaged in 500 ml units, an animal sera used for cell culturing, Recall #T-059-2
Code: Lot #98852
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by telephone, on or about March 30, 1981. Firm initiated recall completed
Distribution: One consignee in White Hall, Illinois
Size & Quantity: 427/500 ml. units were manufactured and distributed
Reason: Product was found to be positive for the presence of BVD virus antigen.

Product: Calf serum packaged in 500 ml glass units, an animal sera used for cell culturing, Recall #T-060-2
Code: Lot #97017
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by letter, March 27, 1981. Firm initiated recall completed
Distribution: Nationwide
Size & Quantity: 282/500 ml units were manufactured, 261 units distributed
Reason: A very low level toxicity problem may exist in certain cell lines.

Product: RPMI 1640 Medium with L-Glutamine packaged in glass bottles, Recall #T-061-2
Code: Lot #98565
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by letter, March 20, 1981. Firm initiated recall completed
Distribution: Maryland, Indiana, Maine
Size & Quantity: Firm estimates none remains on market
Reason: Product is contaminated with bacteria and mold.

Product: Varicella CF Antigen packaged in 5 ml. glass vials, a CF antigen used for diagnosis of varicella antibody in patient serum, Recall #T-062-2
Code: Lot #40421
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by letter, April 6, 1981. Firm initiated recall completed
Distribution: Burlington, North Carolina; Bethesda, Maryland; international
Size & Quantity: 134/5 ml. vials manufactured and 133 vials were shipped
Reason: Antigen was found to have a drop in titer, below the label claim of 1:8.

Product: CMV CF Antigen packaged in 5 ml glass vials, a CF antigen used for diagnosis of CMV antibody in patient serum, Recall #T-063-2
Code: Lot #40524
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by letter, March 12, 1981. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 56/5 ml vials were distributed
Reason: Antigen was found to have a drop in titer and anticomplementary activity.

Product: Adenovirus CF Antiserum packaged in 1 ml. vials, Recall #T-064-2
Code: Lot #39632
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by letter, March 19, 1981. Firm initiated recall completed
Distribution: Nationwide and international
Size & Quantity: 889/1 ml. vials manufactured and 552 vials distributed
Reason: Antisera was found to have a drop in titer.

Product: Rubella Low Positive Control Serum packaged in 1 ml. glass vials, used as a low titer control in the rubella hemagglutination test, which is used to measure rubella virus antibody in patient serum, Recall #T-065-2
Code: Lot #40464
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by letter, April 30, 1981. Firm initiated recall completed
Distribution: Nationwide and international
Size & Quantity: 150 units were manufactured and 112 units distributed
Reason: Control serum was found to have a titer greater than the label claim.

Product: Recovered Human Plasma - For Manufacturing Use Only, Recall #B-004-2
Code: Unit No. 5221
Manufacturer: Murray-Calloway County Public Hospital Corporation, Murray, Kentucky
Recalled by: Manufacturer, by letter, December 14, 1981. Firm initiated recall
Distribution: Tennessee, Alabama, North Carolina (only one unit)
Size & Quantity: Only one unit distributed
Reason: The unit was prepared from a unit of whole blood from which a sample was tested and mistakenly identified as being non-reactive for the hepatitis B surface antigen (HBsAg). The unit was shipped labeled as non-reactive for HBsAg.

Product: A.N.F. Brand Dog Food in 8, 20, and 40 pound multilayer paper bags with plastic liners, Recall #V-014-2
Code: Lot numbers beginning with HP, HA, HN, HS, and HY.
Manufacturer: Ross-Wells, Hanceville, Alabama
Recalled by: Ross-Wells, Mequon, Wisconsin, by telephone and visits, August 24, 1981 thru September 12, 1981. Firm initiated recall complete
Distribution: Nationwide
Size & Quantity: Firm estimates none remains on market
Reason: Possible contamination of product by *Clostridium perfringens* and *Bacillus cereus*.

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Product: Poviderm Solution, Antiseptic-microbicide, Povidine-Iodine USP 7.5%, 16 fluid ounce bottles, Recall #D-053-2
Code: Lot number 1374
Manufacturer: North American Pharmacal, Dearborn, Michigan
Recalled by: Manufacturer, by telephone call to sole consignee on December 4, 1981, followed up by letter of same date. Firm initiated recall complete
Distribution: Michigan
Size & Quantity: Firm estimates that none remains at the wholesale level
Reason: Short fill of containers.

Product: Homogenized, Pasteurized, Vitamin D, Whole Milk in 1/2 gallon cardboard cartons under eight brand names: Meadow Gold All Jersey; Meadow Gold; Albertsons; Maid O' Clover; Janet Lee, IGA, Circle K; and 7-11, Recall #F-044-2
Code: "Nov. 13 1605"
Manufacturer: Beatrice Food Company, Inc.(doing business as Meadow Gold Dairies), Boise, Idaho
Recalled by: Manufacturer, by telephone, November 3, 1981. Firm initiated recall complete
Distribution: Southern Idaho, northeastern Oregon
Size & Quantity: 6,200 half gallon cartons were produced, 75% was distributed
Reason: Milk contaminated with chlorine sanitizing solution from clean-up.

Product: Slivered Almonds and Sliced Almonds packaged in 2 ounce retail cellophane packages, 24/2 ounce packages per case, Recall #F-048/049-2
Code: Slivered - JUL 2682L; Sliced - AUG 382L
Manufacturer: Guys Foods, Division of Borden, Inc., Liberty, Missouri
Recalled by: Manufacturer, by letter and telephone, December 21-22, 1981. Firm initiated recall
Distribution: Arizona, Mississippi, Indiana, Texas, Missouri, Nebraska Iowa, Minnesota, Kansas, Oklahoma,
Size & Quantity: 350 cases of Slivered; 60 cases of Sliced,
Reason: Active insect infestation found in raw materials used to prepare the repacked finished product.

Product: Whole Kernel Corn in #10 cans, Recall #F-050-2
Code: WS 2/505 7 embossed in the end of each can
Manufacturer: Seneca Foods Corporation, East Williamson, New York

Recalled by: Seneca Foods Corporation, Eastern Division, Marion, New York, by telephone, September 18, 1981. Firm initiated recall
Distribution: Florida, Massachusetts, Maryland, Maine, North Carolina, New Hampshire, New Jersey, New York, Pennsylvania and Tennessee
Size & Quantity: Approximately 400-600 cases remain at wholesalers
Reason: Swollen, leaking cans.

Product: Tampax Tampons, Regular, 10's; Tampax Tampons, Super, 10's, Recall #T-053/054-2
Code: None
Manufacturer: Tampax Inc., Palmer, Massachusetts
Recalled by: Royal Supply Company, New York, New York (distributor), by visit, starting December 8, 1981. Firm initiated recall
Distribution: New York City only
Size & Quantity: 120 dozen boxes of super 10's and 120 dozen boxes of regular 10's were distributed
Reason: Labeling on both types of boxes, brochures and wrappers are in Spanish with no English counterpart.

Product: Puritan Manual Resuscitator PMR 2, Recall #T-067-2
Code: Part numbers 133180-133183, 133190-133193
Manufacturer: Puritan Bennett Corporation, Puritan Division, Lenexa, Kansas
Recalled by: Manufacturer, by letter dated, December 14, 1981. Firm initiated recall
Distribution: Nationwide, international and Canada
Size & Quantity: Undetermined
Reason: If resuscitator is dropped in such a manner that the pressure relief valve poppet is struck severely, the release valve cap assembly may break. If this occurs, loose or broken materials from the assembly may work its way into the main air flow pathway of the resuscitator.

Product: Concept Brand Electrosurgical Generator used in conjunction with an electrosurgical pencil in electrosurgery. The generator takes normal 50/60 Hz low frequence power from a wall outlet and converts it into high frequency current that is required for electrosurgery, Recall #T-068-2
Code: Model numbers 9600 and 9601, serial numbers 1002 thru 1375
Manufacturer: Concept Inc., Clearwater, Florida
Recalled by: Manufacturer, by letter, on or about June 1, 1980. Firm initiated recall completed
Distribution: Nationwide and international
Size & Quantity: 162 units distributed

Reason: To recover and update the units to meet the Underwriters Laboratories Approval and label as UL Approved; and to replace the isolation transformer in the units because they had a lower breakdown threshold than the new higher capacity transformer. Some of the original devices failed to function due to transformer failure.

Disposition of Injunctions:

Defendants: H.Ray Evers, M.D., t/a RA-MAR Clinic, Birmingham, Alabama

Nature of Charges: Misbranding a drug after receipt in interstate commerce. Product failed to bear adequate directions for use.

Disposition: April 27, 1981 - The Court of Appeals for the Fifth Circuit refused to grant an injunction, upholding the decision of the District Court; Civil #78-2882, INJ #837.

NOTE:

Recall #D-007-2, 5 gr. Aspirin Tablets, which appeared on the November 11, 1981 Enforcement Report as a Class III, has been extended to include lot #010-0581, exp date 4/83.

Recall #F-034-2, Martha White Brand Enriched Self-Rising Corn Meal Mix, which appeared on the December 23, 1981 Enforcement Report should have been a Class II Recall.

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Product:	Rubroben-1000, Injectable Vitamin B-12 with Vitamin B Complex 10 cc vial, an Rx drug used in the treatment of pernicious anemia and macro cytic anemias combined with vitamin B complex deficiencies, Recall #D-054-2
Code:	"80 K043" exp. date 1/83
Manufacturer:	Carter-Glogau Laboratories Inc., Glendale, Arizona
Recalled by:	Medical Products Panamericana Inc., Miami, Florida (own label distributor), by letter, January 7, 1982. Firm initiated recall
Distribution:	New York, New Jersey, Florida and Puerto Rico
Size & Quantity:	3,362 vials were distributed. The firm estimates 20% to 30% remains on market
Reason:	Subpotency of the vitamin B-12 ingredient.

HE20.4039:

Product: "Sensible Eating Formula," Powdered Meal Replacement containing vitamins and minerals. The powder is mixed with water and taken orally as a meal supplement or replacement, Recall #F-046-2
Code: All codes having the number 1 as the first digit
Manufacturer: Fillmore Foods, Hayward, California
Recalled by: Manufacturer, by telephone, December 10, 1980. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 548 cases were distributed
Reason: Formulation mixup. Product was super potent. Levels of niacin and other vitamins were way above listed levels.

Product: Orquidea Brand Fresh Strawberries, Recall #F-051-2
Code: Not coded, lot was imported December 2, 1981
Manufacturer: Fernando Justo Villamil, Zamora, Michoacan, Mexico (shipper)
Recalled by: William C. Cain Customs Broker, Hidalgo, Texas by telephone, December 4, 1981. Firm initiated recall complete
Distribution: Cleveland, Ohio
Size & Quantity: 6,912 pint baskets recovered from the market
Reason: Product contains Monitor, an unsafe pesticide.

Product: (a) Cott Extra Dry Ginger Ale in 32 fl. oz. glass bottles; and (b) Cott Diet Ginger Ale in 32 fl. oz. glass bottles, Recall #F-060/061-2
Code: (a) 1-H26, 1-H27 or MAR-18-82 (b) no identifiable code
Manufacturer: American Beverage Corporation, College Point, New York
Recalled by: Canada Dry Bottling Co. of New York, College Point, New York. Firm initiated recall for codes 1-H26 and 1-H27 on or about October 30, 1981. Recall for code MAR-18-82 and diet ginger ale (uncoded) began December 9, 1981.
Distribution: Massachusetts, Rhode Island
Size & Quantity: (a) For code 1-H26 and 1-H27: 15,738 cases/6 qts. each case; for code MAR-18-82, 11,100 cases/6 bottles each. (b) Uncoded diet ginger ale: 11,100 cases/6 bottles each.
Reason: The product contains sedimentation and mold.

Product: Medipak Irrigation Tray, stock #46-101 and 46-102, sterile, Recall #T-071/072-2
Code: All lots
Manufacturer: Megaplast, Inc., Richmond, Virginia
Recalled by: Manufacturer, verbally on December 7, 1981, follow-up in writing on December 8, 1981. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 5,000 cases #46-101 and 5,419 cases #46-102 were distributed
Reason: The trays have defective seals which may result in the loss of product sterility.

Product: "Astro" Controls, X-ray controls associated with fluoroscopy and are in daily use, Recall #R-004-2
Code: Model numbers 755-270A and 755-270B; serial numbers 1003-1308
Manufacturer: Picker International, Highland Heights, Ohio
Recalled by: Manufacturer, by letter, November 13, 1981. Firm initiated field correction
Distribution: Nationwide, international and Canada
Size & Quantity: Firm estimates 249 units subject to field correction
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968. Products failed to meet the entrance exposure rate requirements.

Product: Shimadzu Model MC125L-30 Mobile X-Ray Units, Recall #R-005-2
Code: Model 125L-30
Manufacturer: Shimadzu Corporation, Kyoto, Japan
Recalled by: Hansen Medical Enterprises, Inc., San Clemente, California (importer), by letter. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: Approximately 60 units were distributed
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968. Violations included linearity, reproducibility, beam quality and errors in or incomplete user's information.

Product: Sigma Gamma Camera, Recall #R-006-2
Code: Model 400S - serial numbers below 229, Model 410S - serial numbers below 600, Model 420S - serial numbers below 345
Manufacturer: Technicare Corporation, Solon, Ohio
Recalled by: Manufacturer, by field service letters, December, 1978. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 575 units were distributed
Reason: P-scope video display on the sigma gamma camera system could fall from support mast due to failure of aluminum mounting bracket.

Product: Ohio Nuclear/Technicare Series 400, 410, 414, 438 Scintillation Cameras, Recall #R-007-2
Code: Series 400, serial #182-253; Series 410, serial #287-691; Series 414, serial number 100-104; Series 438, serial #100-284
Manufacturer: Technicare Corporation, Solon, Ohio
Recalled by: Manufacturer, by telephone, October 28, 1981 and letter, October 30, 1981. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: 663 units in commerce
Reason: Normal use of unit has been found to cause lower drive mechanism (coupling) to become disengaged from drive motor. Technicare has requested users to remove units from service pending check by factory service representatives.

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Product: Dos Amigos Brand: (a) Frozen Roasted Peeled Whole Chilies With Stems; (b) Frozen Roasted Whole Peeled Chilies Without Stems; (c) Frozen Diced Chilies; (d) Frozen Chilie Strips, packed in 25 pound cartons, Recall #F-052/055-2
Code: Production date codes "1014" and "1015"
Manufacturer: Joy Canning Company, Las Cruces, New Mexico
Recalled by: Manufacturer, by telephone, November 3, 1981 and December 3-4, 1981. Firm initiated recall complete
Distribution: California, New Mexico, Georgia, New Jersey, Texas
Size & Quantity: Firm estimates none remains on market
Reason: Insect damage and worm infestation.

Product: Lady Lee Real Orange Juice from concentrate in one gallon rigid plastic containers, Recall #F-045-2
Code: "Nov 17" stamped on neck of bottle
Manufacturer: Lucky Stores Inc., Dairy Plant, Buena Park, California
Recalled by: Manufacturer, by telephone, November 12, 1981. Firm initiated recall complete
Distribution: Southern California, Nevada
Size & Quantity: Firm estimates none remains on market
Reason: Apparent contamination with cleansing/sanitizing solution resulting in off taste.

Product: "Pride O' the Farm" Snack Bars packaged in aluminum foil packages. The product comes in several flavors: Apple Cinnamon, Raisin Spice, Apricot, Brownie, Coconut, Recall #F-047-2

Code: All lots distributed prior to October 27, 1981

Manufacturer: Southern Food Products Company, Vernon, California

Recalled by: Manufacturer, by letter, October 27, 1981. Firm initiated recall complete

Distribution: Denver, Colorado

Size & Quantity: Firm estimates none remains on market

Reason: Insect infestation.

Product: Steinfeld's Brand Western Acres Home Style Sauerkraut, 32 fluid ounces (1 quart) glass jars, Recall #F-056-2

Code: L121SK1, L121SK2, L121SK3, L121SK4, L131SK1, L131SK2

Manufacturer: Steinfeld's Products Company, Portland, Oregon

Recalled by: Manufacturer, by teletype, November 25, 1981. Firm initiated recall

Distribution: California, Idaho, Oregon, Washington

Size & Quantity: 908 cases were distributed

Reason: Leaking cases among warehouse stock indicated that the sauerkraut had not completely fermented prior to packing.

Product: Cut Wax Beans, generic brand, 15-1/2 oz. (303x406) cans, Recall #F-057-2

Code: 1CWX3/42100 and 1CWX4/42100

Manufacturer: C-B Foods, Division Curtis Burns Inc., Alton, New York

Recalled by: Manufacturer, by telephone, November 23, 1981. Firm initiated recall

Distribution: Maine

Size & Quantity: 210 cases were distributed

Reason: Product contains rodent filth in the form of hairs.

Product: Pasteurized Crabmeat, Special, net weight 12 ounces, Recall #F-058-2

Code: All codes

Manufacturer: Graham & Rollins, Inc., Hampton, Virginia

Recalled by: Manufacturer, by telephone, December 15, 1981 with follow-up letter, December 16, 1981. Firm initiated recall

Distribution: Landover, Maryland and Philadelphia, Pennsylvania

Size & Quantity: Unknown

Reason: Decomposition and swollen cans.

Product: Fast Hemoglobin Control, Recall #T-066-2
Code: Lot number 105150
Manufacturer: Isolab, Inc., Norton, Ohio
Recalled by: Manufacturer, by letter, sent on August 13, 1981. Firm initiated recall completed
Distribution: Nationwide
Size & Quantity: Firm estimates none remains on market
Reason: The control value numbers on some of the insert labels are reversed.

Seizure Actions Filed:

Product: DuraSoft 2 (phemfilcon A) Hydrophilic Contact Lens Bifocal (82-191-943)
Charge: Adulterated - Products are Class III devices and fail to have in effect either an approved application for premarket approval or an exemption for investigational use
Firm: Wesley-Jessen, Inc., Division of Schering Corporation, Chicago, Illinois
Filed: January 4, 1982 - U.S. District Court for the Northern District of Illinois, Eastern Division at Chicago; Civil #82C0013, FDC #63618.

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FDA Enforcement Report

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The FDA Enforcement Report is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

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January 27, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Xylocaine (Lidocaine HCl) 2% Viscous Solution, a topical anesthetic for the mucous membranes of the mouth and pharynx; in 20 ml., 100 ml., and 450 ml. plastic bottles, an Rx drug, Recall #D-055-2
Code:	All lots with EXP dates from 1/82 through 12/84
Manufacturer:	Astra Pharmaceutical Products, Inc., Worcester, Massachusetts
Recalled by:	Manufacturer, by letter, on or about January 18, 1982. Firm initiated recall
Distribution:	Nationwide
Size & Quantity:	Firm estimates 50,000/20 ml., 185,000/100 ml., and 5000/450 ml. units remain on market
Reason:	Possible pseudomonas cepacia contamination.

HE 20

Product: Ganz-Edwards Coronary Infusion Catheter, intended for subselective infusion of solutions into coronary artery branches. The device is intended for use by qualified medical personnel only, Recall #T-070-2
Code: All lots of Model 22-RCA-2.5F
Manufacturer: American Edwards Laboratories, Santa Ana, California
Recalled by: Manufacturer, by letter, sent December 4, 1981. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: Firm estimated 500 catheters were on the market at onset of recall
Reason: Presence of particulate matter in the lumen of the catheter.

Product: American Precut Stockinette Sterile, Catalog #23655, various sizes and plies, and Tomac Speed Roll Sterile Stockinette, Catalog #23653, various sizes and plies, Recall #T-073/074-2
Code: Lot numbers 151000 thru 162999
Manufacturer: Alba Health Care, Division of Alba-Waldensian, Inc., Valdese, North Carolina
Recalled by: Manufacturer, by letter, November 23, 1981. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates 27,552 units were shipped, undetermined amount remaining on the market
Reason: There may be a hole in the product container which may result in the loss of product sterility.

Product: Velcro Fastening Padded Straps attached to the shin pad and/or thigh pad in Cybex II and shin pads and thigh pads in Orthotron units, products are used for measuring isolated joint movement and functional capability and for an isolated joint rehabilitation system; (a) Shin Pads, Cybex II; (b) Thigh Pads, Cybex II; (c) Shin Pads, Orthotron; Recall #T-075/077-2
Code: Cybex II serial #'s C1050169 thru C1050174, C1060175 thru C1060238, C1070239 thru C1070246, Orthotron serial #'s 01050362 thru 01050423, 01060424 thru 01060545 and 01070546 with the exception of 19 units which were sent without the shin pad: 01050365, 01050370, 01050394, 01050404, 01050411, 01050413, 01050427, 01060469, 01060472, 01060478, 01060480, 01060483, 01060469, 01060510, 01060513, 01060517, 01060531, 01060537, 01060539
Manufacturer: Cybex, Division of Lumex, Inc., Ronkonkoma, New York (finished products Cybex II and Orthrotron); Lumex Inc., Bayshore, New York (shin and thigh pad component and parent firm)
Recalled by: Manufacturer, (Cybex, Div. of Lumex Inc., Ronkonkoma, New York) by letter and visit, July 20, 1981. Firm initiated recall

Distribution: Nationwide and international
Size & Quantity: Volume in commerce: Cybex II machines - 78; Orthotron machines - 166; replacement straps - 83
Reason: Velcro material did not meet specifications and may release during use.

Product: Versene, solution packaged in glass bottles, 100 ml, an enzyme used for removing cells from culture vessel and/or tissue, Recall #T-082-2
Code: Lot #99725, EXP date FEB 28 84
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by letter,sent on December 15, 1981. Firm initiated recall
Distribution: Illinois, New Jersey and Nuertingen, West Germany
Size & Quantity: 115 units were distributed and an undetermined amount remains on market
Reason: Product may be contaminated with bacteria.

Product: EMEM w/EBSS and L-Glutamine, a tissue culture media packaged in 100 ml. bottles, Recall #T-083-2
Code: Lot #99618, EXP date FEB 3 84
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by letter, sent on December 15, 1981. Firm initiated recall
Distribution: Massachusetts, Texas, Indiana, New York, California
Size & Quantity: 204 units were distributed, and an undetermined amount remains on market
Reason: Product has random fungal contamination.

Product: Medium 199 2x in HBSS, a tissue culture medium packaged in 100 ml. glass bottles, Recall #T-084-2
Code: Lot #99484, EXP date 6/29/83
Manufacturer: M.A. Bioproducts, Walkersville, Maryland
Recalled by: Manufacturer, by letter, December 15, 1981. Firm initiated recall
Distribution: Detroit, Michigan and the Republic of South Africa
Size & Quantity: 160 units were distributed, and an undetermined amount remains on market
Reason: Product has random fungal contamination.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Specimen Kit, Urine (Midstream), NSN 6530-00-409-8667, disposable, sterile kit consists of 4 1/2 oz. specimen container with cap, 3 povione-iodine towlettes, 2 tissues, patient ID label, male/female instructions for use, Recall #T-079-2
Code: Lot #'s 1JP1, 1JP2, 1JP3 and 1JP4
Manufacturer: Superior Plastic Products Corp., Cumberland, Rhode Island
Recalled by: Manufacturer, by telephone, on September 17, 1981. Firm initiated recall
Distribution: Illinois, New Jersey
Size & Quantity: Approximately 3,390 cases were on the market at onset of recall
Reason: Lack of assurance of sterility of the "sterile" device due to defective packaging.

Product: Fisher Diagnostics Hematall-C Hematology Controls: (a) Hematology Control Normal Level; (b) Hematology Control Abnormal Level, used as quality control material to monitor the accuracy and precision of methods used to determine the parameters routinely included in complete blood counts. Products are supplied in plastic trays containing 6x6 ml. vials, all of which will be either normal controls or abnormal controls, and also in trays containing 5x3 ml. vials containing either normal or abnormal controls. The trays are shipped in polystyrene containers containing a cold pak, Recall #T-080/081-2
Code: (a) product number 3093-32, lot 928-071; product no. 3099-28, lot 930-071; (b) product no. 3095-32, lot 929-071; product 3101-28, lot 931-071
Manufacturer: Fisher Scientific Company, Diagnostics Division, Orangeburg, New York
Recalled by: Manufacturer, by letter, dated July 21, 1981. Firm initiated recall completed
Distribution: Nationwide
Size & Quantity: Firm estimates none remains on market
Reason: Presence of mold in some vials of the subject lots.

Seizure Actions Filed:

Product: Rice Flour (82-256-959)
Charge: Product was held under insanitary conditions whereby it became contaminated with filth
Firm: Riviana Foods, Inc., Memphis, Tennessee
Filed: January 12, 1982 - U.S. District Court for the Eastern District of Missouri, Eastern Division at St. Louis; Civil #82-0058-C(2), FDC #63615.

Product: Macaroni Products (82-284-922 et al)
Charge: Adulterated - Products have been held under insanitary conditions whereby they may have become contaminated with filth
Firm: Olindo Imported Foods, Inc., Rochester, New York
Filed: January 18, 1982 - U.S. District Court for the Western District of New York at Rochester; Civil #82-43(BE), FDC #63617.

NOTE:

Recall #F-045-2, Lady Lee Real Orange Juice from concentrate, which appeared on the January 20, 1982 Enforcement Report should have been a class II recall.

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FDA Enforcement Report

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

February 3, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	Bourns BMED BP 200 Infant Ventilator and Solenoid Assembly repair parts for the unit; and Bourns LS-104 Ventilators. These units are intended for use on both ventilator dependent patients and non-dependent patients, Recall #T-045-2 and T-069-2
Code:	Ventilator serial #'s 9286 and 9888 inclusive. The Solenoid Assembly Repair Parts bear Serial #'s - A490-1/60, A715-1/60 A716-1/60, A815-1/60, B127-1/60, B346-1/60, B828-1/60, C723-1/60, C724-1/60, C886-1/60, D411-1/60, D412-1/60, E240-1/70, E241-1/70, E812-1/70, E813-1/70, and E814-1/70. The Part No. is 54856-00106. Serial numbers for the LS-104 are between 3108 and 3177
Manufacturer:	Bear Medical Systems, also known as Bourns Medical Systems, Riverside, California
Recalled by:	Manufacturer, by letters, November 13, 1981, and January 25, 1982. Firm initiated recall
Distribution:	Nationwide and international
Size & Quantity:	890 Solenoid Assemblies, and 114 LS-104 units to be retrofitted remain on market
Reason:	Devices may have a potentially defective exhalation solenoid assembly. This could result in a delay or cessation of inspiration to neonates.

HE 20. 4039.

Product: "Vive II" Birtcher Defibrillator, Model 493, product is a portable cardiac defibrillator intended for use by qualified professionals only, Recall #T-050-2
Code: Serial #'s 99 through 154
Manufacturer: Birtcher Corporation, El Monte, California
Recalled by: Manufacturer, by telephone, and follow-up certified letters November 18, 1981. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: 34 units remain on market
Reason: Firm is recalling product due to a potentially defective capacitor. A failure of capacitor could prevent proper operation of unit.

Product: Safeguard 3 Line operated defibrillator, Recall #T-056-2
Code: Serial #'s 290, 336, 379, 380, 374, 1001, 1006, 1002, 1003, 1004, 1005, 1007, 1008, 1009, and 1010
Manufacturer: Safeguard Medical System, Inc., Beltsville, Maryland
Recalled by: Manufacturer, by telephone, December 14, 1981. Firm initiated recall
Distribution: Virginia, Florida, New York, Maryland, Canada, Argentina
Size & Quantity: 15 defibrillators were distributed
Reason: Product contains a potentially defective capacitor. A failure of capacitor could prevent proper operation of unit.

Class II - ***A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)***

Product: Angiocath Catheter, an Rx device used to gain and maintain access to the vascular system for purposes of adding or extracting fluids, Recall #T-048-2
Code: All catalog numbers. Lot numbers are not specified in the notification letter
Manufacturer: The Deseret Company, Sandy, Utah, a subsidiary of Warner-Lambert
Recalled by: Manufacturer, by letter, dated January 8, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: Unknown
Reason: There is a potential for separation of the needle from its hub when the needle is withdrawn from the catheter.

Class III - ***A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)***

Product: Orphenadrine Citrate Tablets 100 mg, an Rx oral drug in bottles of 100's, 500's and 1000's, Recall #D-056-2
Code: Lot #0K010, EXP date 1/84
Manufacturer: Inwood Laboratories Inc., Inwood, New York
Recalled by: Manufacturer, by telephone, November 11, 1981 and January 5, 1982 with follow-up letter, dated November 16, 1982. Firm initiated recall complete
Distribution: New York, New Jersey, and Florida
Size & Quantity: Firm estimates none remains on market
Reason: Drug marketed without an approved NDA/ANDA.

Product: Aromatic Fluid Extract Cascara USP, packaged in 2 fluid ounce and 4 fluid ounce bottles, an OTC drug for temporary relief of occasional constipation, Recall #D-057-2
Code: Lot number "34B"
Manufacturer: L.T. York, Brookfield, Missouri
Recalled by: Manufacturer, by letter, January 13, 1982. Firm initiated field correction
Distribution: Midwestern and Southern United States
Size & Quantity: Firm estimates 500 bottles remain on market
Reason: Alcohol content less than USP requirements.

Product: Isosorbide Dinitrate Tablets, an Rx drug for use in cardiovascular disorders. Its basic action is to relax smooth muscle and serve as a vasodilator, Recall #D-058-2
Code: Control number 0H17524
Manufacturer: Barr Laboratories, Northvale, New Jersey
Recalled by: Stayner Pharmaceuticals, Santa Clara, California (distributor), by letter, January 7, 1982. Firm initiated recall
Distribution: Arizona, California and Washington State
Size & Quantity: 451 bottles of 1000 tablets were distributed
Reason: Product is mislabeled - 10 mg. tablets may be labeled as 5 mg. tablets.

Product: Aspirin Tablets, 5 grain in 100, 250, and 500 tablet bottles, Recall #D-059-2
Code: Control No. 6021

Manufacturer: Norwich-Eaton Pharmaceuticals, Norwich, New York
Recalled by: Dixon-Shane Inc., Philadelphia, Pennsylvania, (Repacker/Responsible firm) by telephone with follow-up letter, January 19, 1982. Firm initiated recall
Distribution: One consignee in Philadelphia, Pennsylvania
Size & Quantity: 524 bottles were distributed
Reason: Labeling did not include limitations for use statement and it did not state "manufactured for" or "distributed by" statement as required in 21 CFR, Part 201.1(c).

Product: Canned Black Olives in 7 3/4 ounce cans, Recall #F-059-2
Code: D5W1S/6153
Manufacturer: Early California Foods, Visalia, California
Recalled by: Lucky Stores, Inc., Northern Food Division, San Leandro, California, by telephone and an Operations Bulletin, September 24, 1981. Firm initiated recall complete
Distribution: California, Nevada
Size & Quantity: 1008 cans were subject to recall
Reason: Swollen cans due to age of product.

Product: Durkee Granadaisa Flat Anchovies, Product of Portugal, Recall #F-062-2
Code: 04B06U
Manufacturer: Uniao Conserveria De Algavue (LVA), Portimao, Portugal
Recalled by: Dillon Stores, Hutchinson, Kansas, by issuing a stop sale order November 9, 1981. Firm initiated recall complete
Distribution: Kansas
Size & Quantity: None remains on the market
Reason: Complaint received from Kansas State Department of Health and Environment of leaking (50%) slightly swollen (some) with a fecal odor.

Product: (a) Salted Mixed Nuts with Jumbos in 4 ounce cello bags; (b) Fancy Mix with Peanuts in 5 pound multi-layer paper bags; (c) Fancy Mix in 30 pound cardboard cases; (d) Mixed Nuts w/Cashews in 30 pound cardboard cases, Recall #F-063/066-2
Code: (a) Apr 2682 L; (b) May 382; (c) Apr 2682 May 382; (d) Apr 2682
Manufacturer: Guys Foods, Division of Borden Inc., Liberty, Missouri
Recalled by: Manufacturer, by letter with follow-up telephone calls and visits, January 8, 1982. Firm initiated recall

Distribution: Arizona, Mississippi, Indiana, Texas, Missouri, Nebraska, Iowa, Minnesota, Kansas, Oklahoma

Size & Quantity: (a) 584/24/4 ounce; (b) 77/5 pound; (c) 7/30 pound; (d) 6/30 pound cases in commerce

Reason: Products packed using in part, insect infested whole almonds.

Note: On January 26, 1982, FDA and Bausch & Lomb, Inc., signed a consent agreement regarding that firm's P.A.1. series bifocal soft contact lenses. As part of the agreement the firm consented to stop all sale, commercial distribution, promotion and advertising for the lenses until it has received premarket approval from FDA. Copies of the agreement are available through FDA's Freedom of Information Office, HFI-35, 5600 Fishers Lane, Rockville, Maryland 20857.

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February 10, 1982

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NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Perma Fresh Fruit Punch Concentrate, product is a diet liquid beverage mix in 4 ounce and 16 ounce plastic bottles, Recall #F-067-2
Code:	Lot #D241 and G180
Manufacturer:	Calevas Laboratories, Washington, D.C.
Recalled by:	Manufacturer, by telephone, and letter, January 18, 1982. Firm initiated recall
Distribution:	Washington, D.C., Maryland, Virginia, Pennsylvania, Louisiana
Size & Quantity:	34 small cases (24/4 ounce units/case) and 21 large cases (12/16 ounce units/case) were distributed
Reason:	Product contains FD&C Red #2.

HE 20.4020:

Product: PRO-CUTE (brand) Lotion for dry skin care, 4 fluid ounce and gallon bottles, an OTC skin lotion, Recall #F-069-2
Code: Lot #40-265
Manufacturer: Ferndale Labs Inc., Ferndale, Michigan
Recalled by: Manufacturer, by letter sent on December 14, 1981. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 6,482/4 ounce and 50/1 gallon bottles distributed. Firm estimates less than 10% of distributed amount remains on market
Reason: Bacterial contamination.

Product: Bentley Cardioflo Thermodilution Catheter, intended for use with the Model L1 7000 Cardiac Output Computer, Recall #T-087-2
Code: Model BTD-7L1; lot 47852
Manufacturer: Bentley Laboratories, Inc., Irvine, California
Recalled by: Manufacturer, by letter, December 11, 1981. Firm initiated recall
Distribution: One dealer in Waltham, Massachusetts
Size & Quantity: Firm estimates 190 units remain on market
Reason: The luer hubs at the proximal and distal injection sites may crack.

Product: Tesan Chapless Teat Dip, liquid, OTC, in one gallon, five gallon, 15 gallon & 30 gallon containers, an extension of Recall #V-012-2 which appeared on the December 2, 1981 Enforcement Report
Code: All lots
Manufacturer: Whitmoyer Labs., Inc., Myerstown, Pennsylvania
Recalled by: Manufacturer, by letter, January 21, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 28,439 gallons distributed April 1, 1981 thru January 19, 1982 and 9,681 gallons distributed to private label distributor September 1981 through January 19, 1982
Reason: Subpotent.

***Class III** - A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Heparin Sodium Injection USP, 10,000 units per ml., from beef lung, sterile solution, 4 ml. vials, for subcutaneous or intravenous use, an Rx anticoagulant, Recall #D-060-2
Code: Lot # 238HT, Exp. date 9/82 (correct expiration date). Incorrect expiration date of 9/92 on some vial labels
Manufacturer: The Upjohn Company, Kalamazoo, Michigan
Recalled by: Manufacturer, by letter dated January 12, 1982. Firm initiated recall
Distribution: Nationwide and Belgium
Size & Quantity: Firm estimates 5,000 vials remain on market
Reason: Incorrect expiration date on some vial labels.

Product: Pennwalt Tussionex Suspension (resin complexes of Hydrocodone and Phenyltoloxamine) 900 ml. size bottles, a controlled liquid prescription drug used as an antitussive, for oral administration, Recall #D-061-2
Code: D0331, D0335, D0337, D0338, D0339 (only portions of these lots are under recall)
Manufacturer: Pennwalt Corporation, Pharmaceutical Division, Rochester, New York
Recalled by: Manufacturer, by visit, January 7, 1982. Firm initiated recall
Distribution: Arkansas, Alabama, Georgia, Illinois, Louisiana, Missouri, North Carolina, South Carolina, Tennessee, Texas, Wisconsin
Size & Quantity: Approximately 3900 bottles were distributed
Reason: Resin complexes of hydrocodone and phenyltoloxamine separated from the suspension.

Product: Tartan Pale Dry Ginger Ale Carbonated Soda, 16 ounce non-returnable glass bottles, Recall #F-068-2
Code: Notched date on label - code edge - 08 28 81 (manufacture date)
Manufacturer: Canada Dry Delaware Valley Bottling Company, Philadelphia, Pennsylvania
Recalled by: Manufacturer, by letter, January 11, 1982. Firm initiated recall
Distribution: Pennsylvania, New Jersey, Delaware, Virginia
Size & Quantity: 448 cases of 24 bottles each were distributed
Reason: Mold contamination.

Product: Jelly Beans, Watermelon Flavor, labeled as Wunder Beans, Gourmet, Jelly Beans-Watermelon, in 14 pound cartons, Recall #F-070-2
Code: Lot 2024109
Manufacturer: P.H. Wunderle, Inc., Philadelphia, Pennsylvania
Recalled by: Manufacturer, by telephone, December 16, 1981. Firm initiated recall
Distribution: Ohio, New Jersey, New York, Massachusetts, California
Size & Quantity: 48 cartons were distributed
Reason: Product adulterated with rodent hairs and wood particles.

Product: Radioimmunoassay (RIA) Adrenocorticotropic Hormone (ACTH) Test Kit for in-vitro diagnostic use. Product contains radioactive tracer 125 I-ACTH, reagents, and standards (6) for the measurement of ACTH, Recall #T-078-2

Code: ACTH Kit lot # AT 118B, RIA test standards lot #05/31 EXP 8/82

Manufacturer: International CIS, Gif-Sur-Yvette, France

Recalled by: Damon Diagnostics, Division of Damon Corporation, Needham Heights, Massachusetts, by telephone, November 5, 1981. Firm initiated recall

Distribution: Missouri, Indiana, Massachusetts, Maryland, Tennessee, New Jersey, Oklahoma, Illinois, Michigan, New York, Canada

Size & Quantity: 29 kits were distributed and remain on market

Reason: Some test standard vials were labeled with the wrong reconstitution volume.

NOTE:

Recall #T-056-2, Safeguard 3 line operated defibrillator, which appeared on the February 3, 1982 Enforcement Report as a Class I, has been extended to include serial number 1011, Vive II KP11A116, KP11A117, KP11A118, KP11A119.

Recall #T-075/077-2, a Class II recall which appeared on the January 27, 1982 Enforcement Report should read: Velcro Fastening Padded Straps attached to the shin pad and/or thigh pad in Cyben II and shin pads in Orthotron units. (Thigh pads are not included in the Orthotron units.)

Code numbers for Recall #T-045-2/T-069-2 (Bourns BMED BP 200 Infant Ventilator and Solenoid Assembly repair parts for the unit; and Bourns LS 104 Ventilators) which appeared as a Class I recall on the February 3, 1982 Enforcement Report is being repeated to emphasize that all serial numbers between 9286 and 9888 for the 200 Infant Ventilator and 3107 and 3177 for the LS-104 Ventilators are under recall.

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FDA Enforcement Report

Press Office
Food and Drug Administration

5600 Fishers Lane
Rockville, Md. 20857

301/443-4177

The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions and recalls. The following is an explanation of these actions.

PROSECUTION: A criminal action filed by FDA against a company or individual charging violation of the law. Prosecutions listed below have been filed with a court but not yet tried or concluded.

SEIZURE: An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods until the matter is resolved. The date listed is the date a seizure request is filed, not the date of seizure.

INJUNCTION: A civil action filed by FDA against an individual or company seeking, in most cases, to stop a company from continuing to manufacture or distribute products that are in violation of the law. Injunctions listed have been filed with the court but not concluded.

RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

February 17, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	(a) Red Blood Cells (Human); (b) Single Donor Plasma (Human), Fresh Frozen; (c) Recovered Human Plasma, Recall #B-005/007-2
Code:	(a) 70H07342 - HBsAg reactive, 70H07355 - HBsAg reactive, 41S34193 - HBsAg reactive, 41M63284 - presumptively HBsAg reactive; (b) 41M63284 - presumptively HBsAg reactive; (c) 70H07342 - HBsAg reactive, 70H07355 - HBsAg reactive, 41S34193 - HBsAg reactive
Manufacturer:	American Red Cross Blood Services (ARC), Montgomery, Alabama
Recalled by:	Manufacturer, by telephone. Firm initiated recall complete
Distribution:	Alabama, North Carolina
Size & Quantity:	Firm estimates none remains on market
Reason:	Products which were reactive for hepatitis B surface antigen (HBsAg) or presumptively reactive for HBsAg were released for transfusion or further manufacture.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Heparin Sodium Injection USP, 1,000 units per ml., 10 ml. multiple dose vial, an anticoagulant Rx injectable drug, for subcutaneous or intravenous use, Recall #D-062-2
Code: Lot number 81157 EXP 5/84
Manufacturer: Torigian Laboratories, Inc., Queens Village, New York
Recalled by: Manufacturer, by letter, November 30, 1981. Firm initiated recall
Distribution: One defense depot in Tracy, California
Size & Quantity: FDA estimates approximately 600 vials remain on market
Reason: Short fill.

Product: Septra Suspension in 473 ml., 450 ml., and 100 ml. bottles, Recall #D-063-2
Code: 9F2013, 9F2014, 9F2075, 9F2076, 9F2077, 9I2235, 9J2381, 9J2382, 9J2383, 9J2384
Manufacturer: Burroughs Wellcome Company, Research Triangle Park, North Carolina
Recalled by: Manufacturer, by letter, January 21, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates none remains on market
Reason: The product is subpotent in sulfamethoxazole ingredient.

Product: LaEstrella Casabe Cassava Bread, 5 ounce plastic bags, a product of Dominican Republic, Recall #F-071-2
Code: None
Manufacturer: Leopoldo Gonzales Perez, Santo Domingo, Dominican Republic
Recalled by: Gilda Industries Inc., Hialeah, Florida (own label distributor), by visit, January 6, 1982. Firm initiated recall
Distribution: South Florida
Size & Quantity: Firm estimates none remains on market
Reason: Product is contaminated with insect fragments and rodent hairs.

Product: DeVO2, Model 955, Oxygen Concentrator, used in a home setting to provide low-flow oxygen therapy, Recall #T-088-2
Code: Serial numbers 21875 through 25074 utilizing ASCO USX 8262C14 purge solenoid valve with serial #14379J
Manufacturer: De Vilbiss Company, Health Care Division, Somerset, Pennsylvania
Recalled by: Manufacturer, by letter, February 2, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Approximately 2300 units were distributed that are involved in this recall
Reason: Malfunction of the purge solenoid valve may cause internal fires or rapid oxidation.

Product: (a) IOLAB Intraocular Lens Model 91U; (b) IOLAB Intraocular Lens Model 61; (c) IOLAB Intraocular Lens Model 61B, Recall #T-089/091-2

Code: (a) S/N'S 051779-91U-140 THRU 051779-91U-150; (b) S/N'S 042881-61-1256 THRU 042881-61-1300; (c) S/N'S 070981-61B-601 THRU 070981-61B-603

Manufacturer: IOLAB Corporation, Covina, California

Recalled by: Manufacturer, by telephone, during the month of October Firm initiated recall completed

Distribution: Nationwide

Size & Quantity: Firm estimates none remains on market

Reason: (a) & (b) The devices are mislabeled; (c) The [illegible] misassembled.

Product: Amylotube (Amylase), 100 Tests, a test kit for in-vitro diagnostic use for the quantitative determination of amylase in serum, plasma or urine, Recall #T-092-2

Code: One lot - #810208, EXP date 3/28/82, Catalog #8200-10

Manufacturer. Princeton Biomedix (subsidiary of Becton-Dickinson & Co. at time of recall), Princeton, New Jersey

Recalled by: Manufacturer, by telephone, letter and telegram, initiated August 12, 1981. Firm initiated recall completed

Distribution: Nationwide

Size & Quantity: Firm estimates none remains on market

Reason: The iodine reagent included in the kits may have deteriorated, resulting in falsely elevated patient values.

Product: Monoject brand of Lithium Heparinized Blood Collection Test Tubes (glass tubes with green stoppers), used for hematology and many chemistry lab procedures requiring plasma or whole blood, packed 100 per carton with 10 cartons per case, Recall #T-093-2

Code: Catalog numbers (HRI reorder numbers) - 8881-321254, 8881-321452, 8881-321551, 8881-321759; lot numbers - 06229, 06274, 06319, 06322, 06360, 06402, 06410, 06395

Manufacturer: Sherwood Medical Industries, Inc., Norfolk, Nebraska

Recalled by: Sherwood Medical Industries, Inc., St. Louis, Missouri, by telephone, December 1, 1981 and January 21, 1982. Firm initiated recall completed

Distribution: Sherwood Medical Industries Distribution Centers in California, Texas, Georgia, Illinois, New Jersey

Size & Quantity: Firm estimates none remains on market

Reason: The blood collection tubes were contaminated with ammonia.

Seizure Actions Filed:

Product: WANS Suppositories (82-281-867 et. al)

Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption

Firm: Alcon Laboratories (P.R.) Inc., Humacao, Puerto Rico

Filed: January 11, 1982 - U.S. District Court for the District of Puerto Rico at San Juan; Civil #82-0055, FDC #63620.

Product: Frozen Scallops, labeled in part: "rainbow frozen fresh Seafoods DIST BY RAINBOW VENDING *** SALEM, OR ***" (82-247-953)

Charge: Adulterated - Product consists in part of a decomposed substance by reason of the presence therein of decomposed scallops

Firm: Rainbow Vending & Enterprises, Salem, Oregon

Filed: January 28, 1982 - U. S. District Court for the District of Nevada at Reno; Civil #R-82-26-BRT, FDC #63634.

NOTE: Code numbers for Recall #T-045-2 and T-069-2 (Bourns BMED BP 200 Infant Ventilator and Solenoid Assembly repair parts for the unit; and Bourns LS 104 Ventilators) which appeared as a Class I recall on the February 3, 1982 Enforcement Report is being repeated to emphasize that all serial numbers between 9286 and 9888 for the 200 Infant Ventilator and 3108 and 3177 for the LS-104 Ventilators are under recall.

Dextrostix Brand Reagent Strip, a Class II recall which appeared on the January 6, 1982 Enforcement Report should include under code: **The control number is also found on the bottle carton and may be followed by the letter "A."**

Recall #F-068-2, **Tartan Pale Dry Ginger Ale Carbonated Soda, which appeared as a Class III recall on the February 10, 1982 Enforcement Report should include: FDA was alerted to the problem by New Jersey State Health Department. Philadelphia District Office field examination in conjunction with Pennsylvania Department of Agriculture resulted in an embargo of product in Philadelphia.**

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FDA Enforcement Report

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February 24, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	All Canned Salmon in 7.75 ounce size metal cans produced at NEFCO-Fidalgo Seafoods, Ketchikan, Alaska in 1980 and 1981 The recall includes Pink, Chum, Silver, King and Red Species of Salmon, Recall #F-078-2
Code:	The product under recall can be identified by the letter/numbers "K13" in the second, third and fourth positions of the top line of the two-line code. The "K13" must be proceeded and followed by a letter.
Manufacturer:	NEFCO-Fidalgo Seafoods, Ketchikan, Alaska
Recalled by:	Manufacturer, by letter, February 17, 1982. Firm initiated recall
Distribution:	Nationwide and international
Size & Quantity:	Firm estimates 2.08 million 7.75 ounce cans distributed
Reason:	Some cans may have been damaged when they were formed at the canning plant, permitting the formation in the can of botulinum toxin, a poison that can cause botulism, a possibly fatal disease. See FDA press release P82-4, February 18, 1982.

HF [illegible]

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Island Spring Brand Tofu, 16 ounce package, packaged in a plastic tray with a cellophane sealed top. Tofu is a soybean cake used in soups and vegetable dishes, Recall #F-072-2

Code: Any pull date prior to and including February 4, 1982, indicated by "Sell by FEB4," "2.04" or "2.4"

Manufacturer: Island Spring Inc., Vashon, Washington

Recalled by: Manufacturer, by telephone, January 21, 1982. Firm initiated recall

Distribution: Washington State, Oregon, Alaska, Idaho, Montana

Size & Quantity: Firm estimates 9,000 pounds remain on market

Reason: Product is adulterated with Yersinia enterocolitica which caused yersinia intoxication or infection. The illness mimics appendicitis. The recall was requested by the Washington State Department of Social and Health Services on January 21, 1982 following investigation by FDA, Washington State and King County officials.

Product: High Potency B Complex Vitamins with Vitamin C, labeled under "Radiance" and "Origin" labels, in 50, 100, 250 capsule bottles, Recall #F-073-2

Code: Lots 1461810, 1507212 (Radiance); 4617, 4666, 5014 (Origin)

Manufacturer: Winning Laboratories, Costa Mesa, California

Recalled by: Radiance Products Company/Origin Vitamin Company, City of Industry, California (repacker), by letter, January 15, 1982. Firm initiated recall

Distribution: Nationwide

Size & Quantity: Firm estimates 300,000 capsules remain on market

Reason: The product is labeled as containing niacinamide but actually contains niacin as nicotinic acid.

Product: Blood Tubing Set intended for use with hemodialysis equipment, packaged under the Lifemed and Travenol labels, Recall #T-094-2

Code: Lot numbers L1D001 through L1M099 (letter designation D, E, F, G, H, J, K, L, M)

Manufacturer: Lifemed/Division of Vernitron, Compton, California

Recalled by: Manufacturer, by mailgrams, January 9, 1982, and January 12, 1982 requesting product be put on hold until replaced or field examined. Firm initiated recall

Distribution: Nationwide and international

Size & Quantity: Firm estimates less than 14,000 sets remain on market

Reason: Firm has observed a hole in the blood tubing approximately one inch above the patient connector on either the arterial or venous lines.

Product: (a) Medipak Urethral Catheter Trays, Stock #s 46-200/202 and 46-230/232; (b) Medipak Universal Catheter Trays, Stock #s 46-203/204; (c) Medipak Ear Syringe, Stock#s 46-301, 302, 303, Recall #T-095/097-2

Code: Catheter Trays (Urethral) - Product #46-200, lot #46008001, 46011007, 46101010, 46102014, 46102017; Product #46-201, lot #46008007, 46010003, 46011006, 46102016, 46106005, 46107003; Product #46-202, lot #46101008, 46101014, 46102006, 46103013, 46103015, 46104001, 46105004, 46106003; Catheter Trays (Universal) Product #46-203, lot #46008003, 46008004, 46009001, 46010006 46011005, 46012004, 46012005, 46101001, 46101004, 46101009, 46101012, 46102002, 46103005, 46103011, 46103016, 46104002, 46104019, 46105001, 46105002, 46106007, 46106008, 46106009, 46107001, 46107002, 46107006, 46108002; Catheter Trays (Universal) Product #46-204, lot #46009006, 46010011, 46011003, 46012001, 46012008, 46101002, 46101006, 46102005, 46102011, 46103001, 46103007, 46103012, 46103014, 46104013, 46104015, 46104017, 46104020, 46106004, 46106006, 46108003, 46108004, 46108006, 46108007, 46109001, 46109004; Catheter Trays (Urethral) Product #46-230, lot #46101016, 46104003; Product #46-231, lot #46101019, 46104005; Product #46-232, lot #46101018; Ear Syringes: Product #46-301, lot #46012006, 46103010, 46106001; Product #46-302, lot #46008006, 46008008, 46009003, 46010002, 46010005, 46012002, 46012011, 46102007, 46102018, 46102019, 46104004, 46104007, 46107005, 46108008, 46109003, 46104014; Product #46-303, lot #46009005, 46010007, 46101015, 46104008, 46107004, 46108001, 46102007

Manufacturer: Megaplast, Inc., Richmond, Virginia

Recalled by: Manufacturer, verbally and in writing, January 12, 1982. Firm initiated recall

Distribution: Nationwide

Size & Quantity: Firm estimates 200 cases of catheter trays and 250 cases of ear syringes remain on market

Reason: Defective seals in sterile barrier packaging.

Product: Fluorescent Treponemal Antibody - Absorption (FTA-ABS) Fluoro-kit, 100 Determination Kit; all components in styrofoam box -- all labeled with Clinical Sciences (CSI) label, including test slides, coverslips, dispensing cartridge, reactive control serum, non-reactive control serum, liquid sorbent, phosphate-buffered saline, dropper vial, and directions for use, an in-vitro diagnostic for professional use in syphilis detection, Recall #T-098-2

Code: Catalog #1910, lot #H030

Mafufacturer: Clinical Sciences Inc., Whippany, New Jersey

Recalled by: Manufacturer, by telephone, December 24, 1981 with follow-up letters and reply cards. Firm initiated recall

Distribution: Nationwide, England

Size & Quantity: 50 kits were distributed between October 1 through 16, 1981
Reason: The kit is not reacting at its optimum level.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Psora-Caps (methoxsalen, USP), 10 mg., psoriasis treatment, 100 capsule bottles, an Rx drug, Recall #D-064-2
Code: Lot 50719
Manufacturer: Cord Laboratories, Inc., Broomfield, Colorado
Recalled by: Manufacturer, by letter, February 2, 1982. Firm initiated recall
Distribution: Cleveland, Ohio
Size & Quantity: 729/100 capsule bottles were distributed
Reason: Product is being marketed without an approved New Drug Application.

Product: Iodohippurate Sodium I-131 Injection, 0.2 millicuries/ml., intended for use by physicians as a diagnostic aid in determining renal function, renal blood flow, and urinary tract obstruction, Recall #D-065-2
Code: Lot #'s 461 and 464
Manufacturer: Sorin Biomedica, Vercelli, Italy
Recalled by: Syncor International Corporation, Sylmar, California, by letter, December 22, 1981. Firm initiated recall complete
Distribution: Nationwide
Size & Quantity: None remains on the market
Reason: The vials were inaccurately labeled as to the standard date for calibration.

Product: 7-Up bottled in 10 ounce glass returnable bottles with crown caps, Recall #F-074-2
Code: Lots Y1708, Y3016, Z1507
Manufacturer: R & S Bottling Company, Burlington, Iowa
Recalled by: Manufacturer, by salesmen pick-up, lot Y1708 on or about December 9, 1981 and lots Y3016 and Z1507, January 7, 1982. Firm initiated recall complete
Distribution: Approximate 50 mile radius of Burlington, Iowa
Size & Quantity: Firm estimates none remains on market
Reason: Lot Y1708 - excessive crown dust and lots Y3016 and Z1507 mold/yeast/glass.

Product: (a) Kraft Parkay Margarine, 4 sticks per pound package, (b) Kraft Whipped Margarine, 6 sticks per pound; Kraft Whipped Miracle Brand Margarine, 6 sticks per pound, Recall #F-075/076-2
Code: Pull Dates of "Jan 4-82D" through and including "Feb 14-82D"
Manufacturer: Kraft Inc., Garland, Texas
Recalled by: Kraft Inc., Glenview, Illinois, by teletype, November 10, 1981. Firm initiated recall
Distribution: Colorado, Missouri, Arkansas, Texas, Oklahoma, Kansas, Louisiana
Size & Quantity: 4,200,345 pounds were distributed
Reason: Off-flavor margarine caused by yeast contamination.

Product: Ruba-Tect Rubella Diagnostic Test System for Micro Kaolin Procedure, an in-vitro diagnostic for the detection and quantitation of rubella antibodies in blood serum, 100 test kits and 2000 test kits, Recall #T-099-2
Code: List #7300-24, master lot #29-419-HR and 31-652-HR
Manufacturer: Abbott Laboratories, Diagnostics Division, North Chicago, Illinois
Recalled by: Manufacturer, by mailgram, October 9, 1981. Firm initiated recall completed
Distribution: Nationwide, Canada, Australia, Hong Kong
Size & Quantity: 684 (100 test) and 2 (2000 test) kits were distributed
Reason: The kaolin component of the diagnostic kit was substandard resulting in cloudy test samples which could not be read.

Seizure Actions Filed:

Product: Grapefruit Sections, Canned (82-257-597)
Charge: Product was unfit for food by reason of being held in cans which are swollen and leaking
Firm: Morris Canning Company, Winter Haven, Florida
Filed: January 21, 1982 - U.S. District Court for the Eastern District of Missouri, Eastern Division at St. Louis; Civil #82-0102-C(1), FDC #63633.

Disposition of Prosecutions:

Defendant: Chattanooga Restaurant Supply Corporation, Chattanooga, Tennessee
Nature of Charges: Three counts of holding food in a warehouse under insanitary conditions
Disposition: Defendants pleaded guilty to all counts. The corporation was fined $3,000 and the individual was put on two year's probation. U.S. District Court for the Eastern District of Tennessee at Chattanooga; Criminal #CR-1-81-47.

####

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FDA Enforcement Report

Press Office
Food and Drug Administration
5600 Fishers Lane
Rockville, Md. 20857
301/443-4177

The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

March 3, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	Fenwal Blood Warmer; product code 4R4305 (110 volt) and 4R4306 (220 volt); a medical device used to warm the blood during transfusion to reduce complications associated with the infusion of cold donor blood, Recall #T-085/086-2
Code:	Product code 4R4305 (110 volt): Model BW-3, serial #3500 through 4026, Model BW-4, serial #5001 through 5750, 6500 through 7117; Product code 4R4306 (220 volt): Model BW-3, serial #4037 through 5000; Model BW-4: serial #5751 through 6499, 7160 through 7581
Manufacturer:	Panlmatic Corporation, Elk Grove Village, Illinois
Recalled by:	Travenol Laboratories, Inc., Deerfield, Illinois (distributor), by letter, December 22, 1981. Firm initiated recall
Distribution:	Nationwide, Canada, international
Size & Quantity:	1,895 units were distributed nationwide and 2,135 units were distributed internationally
Reason:	The failure of certain electronic components in unmodified BW-3 and BW-4 Fenwal Blood Warmers can result in the temperature of the warming plates rising above the control point and overheating the blood. This condition can exist even though the temperature indicator may be in the normal range.

HE 20.4039:

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Lytren Brand of Oral Electrolyte Solution. Ready-to-use liquid used for infant feeding as specified by a physician to replace water and electrolytes, packed six 32 fluid ounce cans per case. Lytren is also packaged into firm's Diarrrhea Management kits containing one 32 fluid ounce can of Lytren and 1/8 fluid ounce can of Pro-Sobee, Recall #F-077-2
Code: MKC21, EXP 11/81; MAM23, EXP 2/82; MBM24, EXP 3/82; MFM25, EXP 7/82 (distributed to Puerto Rico only). Lot number MHM26, EXP 9/82 was never distributed by the firm and has been destroyed
Manufacturer: Mead Johnson & Company, Evansville, Indiana
Recalled by: Manufacturer, by letter, October 2-5, 1981. Firm initiated recall complete
Distribution: Nationwide and international
Size & Quantity: Firm estimated 45,000 thirty-two fluid ounce cans remained on market at onset of recall
Reason: Leaking cans.

Product: Becton-Dickinson Plastipak, 3 cc 22 g 1 1/2" Syringe with Luer-Lok Tip. The 3 cc 22 gauge 1 1/2" syringes are individually blister packaged. The units are boxed in shelf cartons of 100. There are 10 shelf cartons per shipping case, Recall #T-100-2
Code: Catalog No. 5574, lot numbers 1G278, 1H028, 1H030, 1H046
Manufacturer: Becton-Dickinson & Company, Canaan, Connecticut
Recalled by: Becton-Dickinson & Company, East Rutherford, New Jersey, by letters dated January 4, 1982. Firm initiated recall
Distribution: Nationwide to 21 states. The recall excludes those states serviced by the Chicago, Illinois distribution center
Size & Quantity: 341,000 units of lot 1H028, 332,900 units of lot 1H046, 341,400 units of lot 1H030, 341,300 units of lot 1G278 were distributed
Reason: Some unit packages may be unsealed, a condition which could compromise product sterility.

Product: R. Wolf Hulka Clips, a medical device implant for tubal occlusion; two clips per sterile package, Recall #T-101-2
Code: Reorder number E 4986.90; lot #X1008; sterilization date 12 81
Manufacturer: Richard Wolf Medical Instruments Corporation, Rosemont, Illinois

Recalled by: Manufacturer, by telephone, on January 29, 1982, requesting return of product with follow-up letters sent on February 2, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 525 packages of two clips each were distributed
Reason: Some of the devices were stapled together during packaging which may compromise their sterility.

Product: HTSH RIA (Daps) Diagnostic Kit, an in-vitro diagnostic radioimmunoassy for the determination of human thyroid stimulating hormone concentration in blood serum, 50 test and 100 test kits, Recall #T-102-2
Code: List #5821-22 (50 test kit) and 5821-24 (100 test kit), master lot number 33-916-HL
Manufacturer: Abbott Laboratories, North Chicago, Illinois
Recalled by: Manufacturer, by telephone, to domestic accounts and teletype to international accounts, October 9/13, 1981 informing them of the problem, advising not to use the affected lots and to destroy material on hand for replacement. Firm initiated recall completed
Distribution: Nationwide, Canada, New Zealand, Germany, Singapore
Size & Quantity: Firm estimates none remain on market
Reason: Some bottles of the Daps Reagent contain insufficient antibody which will affect the precision of the assay.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Bactocill, Oxacillin Sodium, an injectable Rx antibiotic, 1 gm. size only for intramuscular or intravenous use, in units of 10 bottles per carton, Recall #D-066-2
Code: RK1587, RH1577
Manufacturer: Beecham Laboratories, Piscataway, New Jersey
Recalled by: Beecham Laboratories, Div. of Beecham, Inc., Bristol, Tennessee by visit, January 28, 1982. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: 28,960 vials of lot RK1587 and 19,300 vials of lot RH1577 were released for distribution
Reason: Potency declaration omission on some labels.

Product: Jiffy White Cake Mix, 9 ounce box, Recall #F-079-2
Code: 1166
Manufacturer: Chelsea Milling Company, Chelsea, Michigan

Recalled by: Big Bear Stores Company, Columbus, Ohio, by special bulletin, December 29, 1981. Firm initiated recall complete
Distribution: Ohio, West Virginia
Size & Quantity: 598 cases of 24 boxes each were distributed. Firm estimates none remains on market
Reason: Insect infestation.

Product: Stokely Van Camp's Artificially Orange Flavored Gatorade Thirst Quencher in 12 fluid ounce cans, Recall #F-080-2
Code: VG 239 D
Manufacturer: Stokely Van Camp, Inc., Dallas, Texas
Recalled by: Manufacturer, by telephone, January 27, 1982. Firm initiated recall complete
Distribution: Oklahoma City, Oklahoma
Size & Quantity: 51 cases of 24/12 ounce cans recovered from the market
Reason: Microleaks, product deterioration (discoloration), can liner breakdown and product leaking from microleaks at pull tabs on can lids.

Product: Nifda Brand Worcestershire Sauce, in one gallon plastic containers, packed 4/1 gallon containers per case, Recall #F-081-2
Code: 4381E (stamped on case only)
Manufacturer: Doxsee Food Corporation, Terre Haute, Indiana
Recalled by: Doxsee Food Corporation, Baltimore, Maryland, by telephone, November 21, 1981 and January 20, 1982. Firm initiated recall complete
Distribution: Ohio, Wisconsin
Size & Quantity: 20 cases each containing four one gallon containers were distributed
Reason: Yeast contamination causing fermentation of product.

Product: Wendy's Celery Seed Dressing, one gallon plastic containers, packed 4 one gallon containers per case, Recall #F-082-2
Code: 4581B, 4681D, 4881B stamped on case only
Manufacturer: Doxsee Food Corporation, Terre Haute, Indiana
Recalled by: Doxsee Food Corporation, Baltimore, Maryland by letter, December 1-2, 1981. Firm initiated recall complete
Distribution: Iowa, Nebraska, Kansas, Missouri, Illinois, Indiana, Kentucky
Size & Quantity: Firm estimates none remains on market
Reason: Yeast contamination causing fermentation.

Product: Pork and Beans and Vegetable Soup, labeled under the "Deseret Brand" label and in #303 cans, Recall #F-083/084-2
Code: All products made in 1979, 1980, 1981
Manufacturer: LDS Welfare Cannery, Los Angeles Area Cannery, Los Angeles, California
Recalled by: LDS Church Welfare System, Salt Lake City, Utah, by visit and letter, August 5-6, 1981. Firm initiated recall
Distribution: Southern California, Nevada, Hawaii
Size & Quantity: Unknown
Reason: Questionable processing practices and a lack of GMP's for low acid canned foods.

Product: Eskalab Disposable 5 Microliter Pipettes, used by medical personnel in the diagnosis of certain diseases or conditions, Recall #T-104-2
Code: Lot number C-7356
Manufacturer: Smitn Kline Instruments, Inc., Sunnyvale, California
Recalled by: Manufacturer, by telephone, November 25, 1981 and follow-up letter, December 1, 1981. Firm initiated recall completed
Distribution: Nationwide
Size & Quantity: 465 boxes were distributed
Reason: A number of 10 microliter pipettes were mistakenly placed in boxes labeled as containing only 5 microliter pipettes.

Product: "Droncit" (Praziquantel) Tablets, 23 mg., feline cestocide tablets, oral (cat wormer), an Rx vet drug, Recall #V-015-2
Code: Lot number 128002
Manufacturer: Bayvet Division of Cutter Laboratories, Inc., Shawnee, Kansas
Recalled by: Manufacturer, by letter, dated January 20, 1982 and January 22, 1982. Firm initiated field correction
Distribution: Alabama, Arizona, Louisiana, Colorado, Florida, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Utah, Virginia, Washington, Wisconsin
Size & Quantity: 2991 bottles shipped
Reason: Package insert mix-up.

Seizure Actions Filed:

Product: Multiple Stored Foods (82-279-110 et al)
Charge: Adulterated - All lots have been held under insanitary conditions and some lots contain insect fragments and excreta
Firm: Yick Fung, Seattle, Washington
Filed: January 29, 1982 - U.S. District Court for the Western District of Washington at Seattle; Civil #C82-110, FDC 63637.

Product: Multiple - Flour and Rice (82-254-358)
Charge: Adulterated - All products were held under insanitary conditions and one lot is rodent gnawed and contains rodent hairs
Firm: Bay State Food Company, Inc., Woburn, Massachusetts
Filed: February 2, 1982 - U.S. District Court for the District of Massachusetts at Boston; Civil #82-0274 MA, FDC #63636.

Product: Frozen Concentrated Orange Juice (FCOJ) (82-261-871)
Charge: Adulterated - Product contains turmeric. Misbranded - Labeling is false and misleading; fails to conform to standard of identity; and fails to state product contains turmeric
Firm: Fresh Pak Foods, Weslaco, Texas
Filed: February 4, 1982 - U.S. District Court for the Southern District of Iowa, Central Division; Civil #82-55-D, FDC #63642.

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March 10, 1982

Recalls and Field Corrections:

Class I - ***A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.***

Product:	Nursoy Concentrated Liquid, 13 fluid ounce cans, and Nursoy Ready To Feed, 32 fluid ounce cans, soy protein formulas for infants and children with specific feeding needs, Recall #F-095/096-2
Code:	The single line codes on the ends of the cans being recalled are A26M, B2M and B9M for Nursoy Concentrated Liquid and A28M and B11M for Nursoy Ready to Feed. The codes may be preceded or followed by a number such as 1, 2, 3, which can be ignored
Manufacturer:	Wyeth Laboratories, Inc., Mason, Michigan
Recalled by:	Wyeth Laboratories, Philadelphia, Pennsylvania, by telephone and mailgram, March 4, 1982 and letters, March 5, 1982. Firm initiated recall. See FDA press release P82-6, March 3, 1982
Distribution:	Nationwide
Size & Quantity:	Approximately 90,336/13 ounce cans of Nursoy Concentrate and 2,568/32 ounce cans of Nursoy Ready To Feed have been distributed.
Reason:	Product is deficient in nutritional content in that it does not contain Vitamin B6 (pyridoxine hydrochloride).

HE

***Class II** - A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Longs Hi B-Complex with Iron Capsules, packed in 100 capsule plastic bottles, Recall #F-086-2
Code: P 91181
Manufacturer: Fresh Labs., Inc., Warren, Michigan
Recalled by: Longs Drug Stores, Inc., Walnut Creek, California, by store bulletin, March 21, 1980. Firm initiated recall complete
Distribution: Alaska, Arizona, California, Hawaii, Nevada, Oregon
Size & Quantity: 4,824 bottles of 100 capsules were distributed
Reason: Product was formulated with niacin instead of niacinamide.

Product: Disposable Yankauer Surgical Suction Instrument; used for suctioning fluid during surgery, an Rx device, Recall #T-108-2
Code: Lot #200010912
Manufacturer: Narco Scientific Pilling Division, Fort Washington, Pennsylvania
Recalled by: Manufacturer, by telephone, February 9, 1982 with follow-up mailgrams and letters. Firm initiated recall
Distribution: Alabama, Arizona, Colorado, Connecticut, Georgia, Kansas, Kentucky, Maryland, Massachusetts, Missouri, Minnesota, Ohio, Pennsylvania, Texas, Wisconsin
Size & Quantity: 136 cases distributed
Reason: Lack of assurance of sterility of the device due to defective packaging.

Product: Carousels used with Abbott Models ABA-100, ABA-200, and VP Clinical Chemistry Analyzers. Uses include cardiac and enzyme testing, Recall #T-110-2
Code: 8110 & 8111 located on inside wall of carousel
Manufacturer: Technical Plastic, Inc., Terrell, Texas
Recalled by: Abbott Laboratories, Inc., Diagnostics Division, Irving, Texas, by telephone, followed up by letters, February 1, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: 113 units were distributed
Reason: Molding defect in carousel which causes inaccurate results.

Product:	Critikon OxyTrode Sensors, single use devices for use with the Critikon OxyTrak Analyzer for measuring oxygen in the blood during open heart surgery, (a) 1/4 inch pediatric; (b) 3/8 inch arterial; (c) 1/2 inch venous, Recall #T-112/114-2
Code:	All lots of (a) catalog #3052, (b) catalog #3054, (c) catalog #3056
Manufacturer:	Critikon Inc., Southington, Connecticut
Recalled by:	Critikon Inc., Tampa, Florida, by telephone and letter, February 4, 1982. Firm initiated recall
Distribution:	Nationwide and international
Size & Quantity:	Firm estimates 400 cases of 10 units each remain on market
Reason:	Non-sterility.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product:	Tomato Catsup, (a) Meadowdale brand in 24 ounce bottles; (b) Chatham brand in 32 ounce glass bottles, Recall #F-085-2
Code:	(a) Bottles: P19YY; Case: A19YY; (b) Bottles: P19KY; Case: 1A19KY
Manufacturer:	Nass Foods Ind., Portland, Indiana
Recalled by:	Manufacturer, by visit, January 28, 1982. Firm initiated recall complete
Distribution:	Michigan
Size & Quantity:	None remains on market
Reason:	Mold count exceeds FDA Compliance Policy Guidelines for tomato catsup.

Product:	Hemoglobin Test Reagent, for the quantitative determination of hemoglobin in whole blood, for in-vitro diagnostic use, 100 test or 25 test tubes per kit, Recall #T-103-2
Code:	Lot numbers 01986, 02276, 02906, 02946, 03106, 03176, 03406, 03526, 10096, 10156, 10266, 10296, 10376, 10556, 10716, 11116, 11466
Manufacturer:	Bio-Dynamics/Puerto Rico/Punto Oro Industrial Development, Ponce, Puerto Rico
Recalled by:	Bio-Dynamics/BMC, Indianapolis, Indiana, by letter, dated December 28, 1981, requesting to check stocks and return all colorless reagent. Firm initiated recall
Distribution:	Nationwide
Size & Quantity:	Firm estimates very little remains or market
Reason:	Some tubes contain a colorless reagent instead of a yellow colored reagent which results in higher values for hemoglobin.

Product: Intermedics Posterior Chamber Intraocular Lenses, "J" Loop, intended for implantation by qualified physicians, (a) Model 019K, diopter 22.00, (b) Model 019J, diopter 20.00, Recall #T-105/106-2

Code: (a) serial #79201 through 79209; (b) serial #79232 through 79240

Manufacturer: Intermedics Intraocular, Inc., Pasadena, California

Recalled by: Manufacturer, by telephone, November 5, 1981. Firm initiated recall complete

Distribution: Nationwide

Size & Quantity: Firm estimates none remains on market

Reason: The Model 019K, diopter 22.00 was labeled as Model 019J, diopter 20.00 and vice versa.

Product: Becton-Dickinson Beta Human Chorionic Gonadotropin (hCG) Radioimmunoassay (RIA) Kit (125I), used for the qualitative and quantitative measurements of hormone levels of serum, plasma, or urine in order to diagnose human pregnancy. Product consists of a kit containing vials of radioactive tracers, antisera, and standards, with enough material for the preparation of 100 sample tubes, Recall #T-109-2

Code: Catalog number 254410, lot #GN9911, GN9912, GN9912A, GN9921, EXP date FEB 1, 1982

Manufacturer: Becton-Dickinson Immunodiagnostics, Orangeburg, New York

Recalled by: Manufacturer, by letter, January 7, 1982. Firm initiated recall complete

Distribution: Nationwide and international

Size & Quantity: Firm estimates none remains on market

Reason: The device is considered misbranded because the firm introduced new assay instructional manuals, eliminating one of the four previously recommended assay methods and modifying another, because of complaints of border line assay results.

Product: Cordis French 6 Ducor Angiographic Catheter labeled for use with 0.035 inch guidewire and with "Use Before" dates of July 1984 and earlier, an Rx device used to deliver radiopaque media to selected sites in the vascular system, Recall #T-111-2

Code: Catalog numbers: 521-632, 521-633, 521-635, 522-632, 522-633, 523-614, 523-615, 523-616, 523-617, 523-640, 523-642, 523-644, 523-651, 523-652, 523-660, 523-661, 523-663, 523-670 with use before dates of July 1984 and earlier

Manufacturer: Cordis Corporation, Miami, Florida

Recalled by: Manufacturer, by letter, February 5, 1982. Firm initiated recall

Distribution: Nationwide and international

Size & Quantity: Firm estimates 10,000 remain on market

Reason: The catheter may have an interior diameter too small to accept a 0.035 inch guidewire.

Product: Tryptic Soy Agar with 5% Sheep Blood, diagnostic media in a 100 x 15 mm petri dish vol. 20 ml., Recall #T-115-2

Code: 2012501 with a March 15, 1982 EXP date

Manufacturer: Granite Diagnostics, Inc., Burlington, North Carolina

Recalled by: Manufacturer, by telephone, February 1, 1982. Firm initiated recall complete

Distribution: Virginia, North Carolina, Pennsylvania, South Carolina

Size & Quantity: Firm estimates that none remains on market

Reason: The firm found viable microbial contamination in the reserve stock.

Complaints For Injunction Filed:

Against: Wesley-Jessen, Inc., Division of Schering Corporation, Chicago, Illinois and Grin B. Stine, President; Samual Loshaek, Vice President and Director, Research and Development; and David Taber, Director Regulatory Affairs

Product: Durasoft 2 (phemfilcon A) Hydrophilic Contact Lens Bifocal (82-291-943)

Charge: Adulterated - The article is a Class III medical device which has in effect neither an approved pre-market approval nor an exemption for investigational use

Filed: February 16, 1982 - U.S. District Court for the Northern District of Illinois, Eastern Division at Chicago; Civil #82C0874, INJ #999.

Disposition of Injunctions:

Defendant: Manhattan Bakery, Atlanta, Georgia

Nature of Charge: Insanitary conditions and receipt of adulterated articles from interstate commerce

Disposition: Permanent injunction prohibiting defendants from continuing the insanitary conditions that existed at the bakery and proffering for delivery adulterated articles received from interstate commerce. U.S. District Court for the Northern District of Georgia at Atlanta; Injunction #994.

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March 17, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	Normal Serum Albumin (Human) USP 5% under the Albuminar-5 brand name, 250 ml. bottle. The product is used in regulating the volume of circulating blood in cases of shock, burns, and hypoproteinemia, an Rx product, Recall #B-008-2
Code:	Lot #V3109
Manufacturer:	Armour Pharmaceutical Company, Kankakee, Illinois
Recalled by:	Manufacturer, by mailgram, February 2, 1982. Firm initiated recall
Distribution:	Nationwide
Size & Quantity:	Firm estimates 700 units remain on market
Reason:	Serious adverse reactions reported following administration of product.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

HE 20. 4039.

Product: (a) Pink Peppercorns packed in consumer size packages of 1.5 ounces under the Dean and De Luca label and in one kg. packages that were unlabeled; (b) Pink Pepper Mustard in 7 1/2 ounce and 21 ounce jars under the Paul Corcellet label, Recall #F-087/088-2
Code: None
Manufacturer: (a) La Taste, Forcalquier, France; (b) Paul Corcellet, Paris, France
Recalled by: Dean & De Luca, Imports, Inc., New York, New York, by letter, on or about February 24, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Approximately 106 pounds of pink peppercorns and 82 cases (696 jars) of 7 1/2 ounce jars and 11 cases (132 jars) of 21 ounce jars of pink pepper mustard were distributed
Reason: Pink peppercorn is not an approved food additive.

Product: Chocolate Covered Marshmallow Easter Eggs in one dozen egg carton-type boxes, Recall #F-089/090-2
Code: A1248B, B1248B, A1248C, B1248C, A1247B, B1247B, A1247C, B1247C, A1247D, B1247D, A1247E, B1247E, A1247F, B1247F, A1247G, B1247G
Manufacture: Zachary Confections, Inc., Chicago, Illinois
Recalled by: Manufacturer, by telephone, February 18, 1982. Firm initiated recall
Distribution: New York, Wisconsin, California, Illinois, Nebraska, Missouri, Michigan, New Jersey, Oklahoma, Kansas
Size & Quantity: Firm estimates none remains on market
Reason: The chocolate compound coating used in the manufacturer of the eggs was contaminated with salmonella bacteria.

Product: Mi-Mark Endometrial Biopsy Set, 3.5 mm., an Rx device used to collect and prepare sample of uterine tissue, sterile, Recall #T-117-2
Code: Lot #0981A
Manufacturer: Simpson/Bayse Inc., Wilmington, Delaware
Recalled by: Manufacturer, by letter, February 26, 1982 with instructions to visually examine each product and return those that were defective. Reply cards were enclosed with letter. Firm initiated recall
Distribution: Nationwide, Canada, Switzerland, Hong Kong, Japan
Size & Quantity: Approximately 15,000 units are in commerce
Reason: Sterility of product is compromised due to unsealed ends of pouch.

Product: (a) Whole Blood (Human); (b) Red Blood Cells (Human); (c) Red Blood Cells (Human), Washed; (d) Red Blood Cells (Human), Deglycerolized; (e) Single Donor Plasma (Human), Fresh Frozen; (f) Platelet Concentrate (Human); (g) Cryoprecipitated Antihemophilic Factor (Human); (h) Recovered Human Plasma, Recall #B-009/016-2

Code: (a) 2468T, 2276R, 4600X, 9625E, 9683E, 3862S, 2478T, 5289X, 5474X, 5594X, 5639X, 5644X, 4701S, 6223X, 3326T, 9999X, 8768S, 2959T, 5024H; (b) 3732S, 4641X, 4630X, 4631X, 4636X, 4643X, 4723X, 9650E, 4742X, 4743X, 4787X, 4127S, 5309X, 6228X, 4141S, 4376S, 4401S, 5574X, 5697X, 4675S, 4696S, 6133X, 4702S, 4703S, 4704S, 4705S, 4706S, 4707S, 4708S, 4709S, 4711S, 4712S, 4713S, 4715S, 4716S, 4718S, 4719S, 4720S, 4721S, 4722S, 4769S, 5920S, 2804T, 7790S, 2727R, 8042S, 7689S, 3247H, 9666E; (c) 9658E, 3813S, 3814S, 3864S, 4717S, 8492S, (d) 4710S; (e) 3732S, 3813S, 3814S, 4742X, 4787X, 4127S, 4141S, 4376S, 4401S, 4696S, 4702S, 4703S, 4704S, 4705S, 4706S, 4707S, 4708S, 4709S, 4710S, 4712S, 4713S, 4715S, 4716S, 4717S, 4718S, 4719S, 4720S, 4721S, 4722S, 4769S, 5920S, 7790S, 8042S, 8492S, 7689S, 4743X; (f) 3732S, 3813S, 4742X, 4743X, 4787X, 4127S, 4141S, 4376S, 4401S, 5697X, 4696S, 6133X, 4702S, 4703S, 4704S, 4705S, 4706S, 4707S, 4708S, 4709S, 4710S, 4711S, 4712S, 4713S, 4715S, 4716S, 4717S, 4718S, 4719S, 4720S, 4721S, 4722S, 4769S, 5920S, 7790S, 8042S, 8492S, 7689S, 564K, 3814S, (g) 4636X, 4641X; (h) 4641X, 4631X, 4636X, 9650E, 9658E, 9666E, 5309X, 5574X, 5697X, 4675S, 6133X, 4711S, 6228X, 2727R, 4723X, 4643X, 3864S,

Manufacturer: Belle Bonfils Memorial Blood Center, Denver, Colorado

Recalled by: Manufacturer, by telephone, December 14, 1981. Firm initiated recall

Distribution: Colorado, Kansas, Florida, New York, California

Size & Quantity: 170 distributed products have been identified

Reason: Products which were presumptively reactive for hepatitis B surface antigen (HBsAg) or could not be correlated to specific results within a series where presumptive reactives were noted or where units collected subsequent to these donations were distributed.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Meclizine HCl Tablets, 12.5 mg., USP, an OTC drug used for prevention and treatment of motion sickness, Recall #D-067-2

Code: Lot numbers 33795, 34923

Manufacturer: Richlyn Laboratories, Inc., Philadelphia, Pennsylvania

Recalled by: Manufacturer, by letter, March 1, 1982. Firm initiated recall

Distribution: Illinois, New Jersey, Pennsylvania, New York, California, Maryland, Ohio, Kentucky

Size & Quantity: 779,200 tablets of lot 33795 and 685,900 tablets of lot 34923 were distributed

Reason: Product failed USP disintegration requirements.

Product: "Safeway" Brand All-Purpose Grind Coffee in one and two pound paper bags, Recall #F-091-2
Code: 3-22-D
Manufacturer: Safeway, Inc., Brookside Division, Dallas, Texas
Recalled by: Manufacturer, by telephone followed by store bulletin, February 3, 1982. Firm initiated recall
Distribution: Delaware, Louisiana, Pennsylvania, Maryland, Texas, Virginia
Size & Quantity: 246 cases 12/1 pound and 260 cases 6/2 pound bags were distributed
Reason: Rodent contamination.

Product: 16 ounce cans of Cut Green Beans, French Style Sliced Green Beans, and Short Cut and Pieces Green Beans. There are four brands: Kuner, Stokely-Van Camp, Mile High and Columbine, Recall #F-092/094-2
Code: Case carton codes - DH252*, DH253*, DH258*, DH259*, DH260*, DH265*, the asterisk may be an A, B, or C
Manufacturer: Kuner-Empson Company, Division of Stokely-Van Camp, Brighton, Colorado
Recalled by: Manufacturer, by letter, January 26, 1982 and telephone, February 1, 1982. Firm initiated recall
Distribution: Kansas, Oklahoma, Arizona, California, Colorado, Wyoming, New Mexico, Texas
Size & Quantity: Undetermined
Reason: Swells, due to post-process contamination, apparently caused by can seam problems.

Product: ANA/AMA Biopak Colorimetric Kit, 40 determinations kit, with eight component groups in a styrofoam box, all labeled with Bioware label. The product is an in-vitro diagnostic for professional use primarily in lupus erythmatosus detection, Recall #T-107-2
Code: Lot numbers 74920H054, 74920H055 expires 3-17-82; lot 74920H060 expires 4-2-82. All lots bear catalog #74920
Manufacturer: Clinical Sciences Inc., Whippany, New Jersey
Recalled by: Bioware Products, Whippany, New Jersey, by telephone, January 8, 1982 with follow-up letters and reply cards mailed January 12, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 20 kits of lot 74920H054, 14 kits of lot 74920H055, 10 kits of lot 74920H060 were distributed
Reason: Component mixup at time of packaging. An orange-masked six-well slide instead of the black masked slide may be included in the kit.

Seizure Actions Filed:

Product: Hydralazine HCl, Hydrochlorothiazide and Reserpine Tablets (81-311-441)
Charge: Failed USP content uniformity test for reserpine active ingredient
Firm: Zenith Laboratories, Northvale, New Jersey
Filed: January 14, 1982 - U.S. District Court for the District of New Jersey at Newark; Civil #82-119, FDC #63598.

Product: "Fresn Pak Foods, Inc. *** Concentrated Orange Juice for Manufacturing *** McAllen, Texas ***" (82-345-781)
Charge: Adulterated - Turmeric, has been added so as to make it appear better or of greater value
Firm: Fresh Pak Foods, Inc., McAllen, Texas
Filed: February 24, 1982 - U.S. District Court for the Northern District of California at San Francisco; Civil #C-82-0770-WHO, FDC #63641.

Product: Peanut Butter (82-222-722)
Charge: Adulterated - Product has been prepared and packed under insanitary conditions whereby it may have become contaminated with filth
Firm: Portales Valley Mills, Portales, New Mexico
Filed: February 16, 1982 - U.S. District Court for the Western District of Texas at San Antonio; Civil #SA 82 CA-173, FDC #63654.

Product: Various Foods (DOC 82-276-329)
Charge: Products were held under insanitary conditions
Firm: Smith & Son Wholesale Company, Inc., Tullahoma, Tennessee
Filed: March 2, 1982 - U.S. District Court for the Eastern District of Tennessee, Winchester Division; Civil #CIV-4-82-19, FDC #63660.

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FDA Enforcement Report

Press Office
Food and Drug Administration
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The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

PROSECUTION: A criminal action filed by FDA against a company or individual charging violation of the law. Prosecutions listed below have been filed with a court but not yet tried or concluded.

SEIZURE: An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods until the matter is resolved. The date listed is the date a seizure request is filed, not the date of seizure.

INJUNCTION: A civil action filed by FDA against an individual or company seeking, in most cases, to stop a company from continuing to manufacture or distribute products that are in violation of the law. Injunctions listed have been filed with the court but not concluded.

RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

March 24, 1982

Recalls and Field Corrections:

Class I - ***A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.***

Product: (a) SMA Iron Fortified Concentrated Liquid, Infant Formula, 13 fluid ounce cans, packed 24/13 fluid ounce cans per case; (b) SMA Iron Fortified Ready-To-Feed Infant Formula, 32 fluid ounce cans, packed 6/32 fluid ounce cans per case, (c) SMA Powder Iron Fortified Infant Formula, 16 ounce cans, packed 12/16 ounce cans per case; (d) SMA E-Z Nurser Ready-to-Feed Iron Fortified Infant Formula, packed 48/4 ounce nursettes per case, Recall #F-102/105-2

Code: Code numbers between A25M through A31M inclusive or B1M through B15M inclusive. The code numbers are embossed on the top of the cans and are printed on the labels of the bottles. The code numbers may be preceded or followed by a number such as 1, 2, or 3, which can be ignored. Example of code: 2A25M

Manufacturer: Wyeth Laboratories, Inc., Mason, Michigan

Recalled by: Wyeth Laboratories Inc., Philadelphia, Pennsylvania, by mailgrams and telephone. Firm initiated recall. See FDA press release P82-8, March 12, 1982

Distribution: Nationwide

Size & Quantity: Firm estimates (a) 1,938,048 cans; (b) 455,552 cans; (c) 4,836 cans; (d) 5,760 bottles were distributed

Reason: Products are deficient in vitamin B6, an essential nutrient for infants. These lots do contain vitamin B6 but in amounts less than that stated on the label.

HE 20.4039.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Dihydroergotoxine Mesylate 1.0 mg. Sublingual Tablets, an Rx drug which is used as an adrenergic blocking agent and is sold in bottles of 500 tablets, Recall #D-068-2
Code: Control #8116-07, EXP 5/83
Manufacturer: Pharmadyne Laboratories Inc., Elmwood Park, New Jersey
Recalled by: Bioline Laboratories Inc., Brooklyn, New York, by telephone on or about August 19, 1981. Firm initiated recall complete
Distribution: Alabama, Indiana, Kentucky, Massachusetts, Missouri, North Carolina, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Tennessee, Virginia
Size & Quantity: Firm estimates none remains on market
Reason: Mislabeled. Product contained tablets that were placebos.

Product: (a) "Food Club" and "Farm Pac" Brand Pasteurized Homogenized Milk in quart, one-half gallon and one gallon containers; (b) Low-Fat 1/2% Milk in one gallon containers; and (c) Chocolate Milk in quart containers, Recall #F-097/099-2
Code: Pull date code 2/4 - pasteurized homogenized milk and lowfat 1/2% milk; 2/6 - chocolate milk
Manufacturer: Clardy's, Roswell, New Mexico
Recalled by: Manufacturer, by telephone, February 1, 1982. Firm initiated recall complete
Distribution: Texas, New Mexico
Size & Quantity: Firm estimates a total of 8626 gallons of pasteurized homogenized milk, 1800 gallons lowfat 1/2% milk, 4500 half gallons pasteurized homogenized milk, 1000 quarts pasteurized homogenized milk and 970 quarts chocolate milk were distributed
Reason: Penicillin contamination. Texas State Health Department discovered the problem and notified the New Mexico health state officials. Following notification of the problem by Texas officials, New Mexico officials supervised the return and disposition of the recalled products.

Product: Chocolate Enrobed Cookies labeled as follows: (a) Salerno Mint Creme Cookies Patties, net weight 10 ounces; (b) Salerno Fudge Sundaes Cookies, net weight 9 1/2 ounces; Recall #F-100/101-2
Code: (a) 4H0808, 5H0808; (b) 1H0815;
Manufacturer: Salerno Megowen Biscuit Company, Niles, Illinois (cookies); Blommer Chocolate Company, Chicago, Illinois (chocolate compound coating)

Recalled by: Salerno Megowen Biscuit Company, by visit, February 16, 1982. Firm initiated recall complete

Distribution: Northern Illinois, northwest Indiana, southwest Michigan and northwestern Iowa

Size & Quantity: Firm estimates none remains on market

Reason: Compound coating used to enrobe the cookies was contaminated with salmonella.

Product: Chocolate compound coating also known as confectioner's in 10 pound molded blocks and bulk liquid shipped under the following names: (a) California Compound Coating (bulk liquid), (b) K-Lite Compound Coating (bulk liquid). This chocolate product is used in further manufacturing of cookies and candies, Recall #F-107/108-2

Code: Products produced between February 5, 1982 and February 15, 1982 with the following batch numbers: (a) U10 through U15; (b) U5, U6, U7, U10, U11. The bulk product is not identified with the batch numbers

Manufacturer: The Blommer Chocolate Company, Chicago, Illinois

Recalled by: Manufacturer, by telephone, February 16, 1982. Firm initiated recall

Distribution: Illinois, Wisconsin

Size & Quantity: 81,840 pounds of the California Coating and 45,000 pounds of the K-Lite Coating were distributed

Reason: The chocolate compound coating is contaminated with salmonella bacteria.

Product: All canned salmon in 7.75 ounce size metal cans produced by the manufacturer, Recall #F-109-2

Code: All production between September 1, 1981 and February 25, 1982

Manufacturer: Perfection Smokery, Inc., Seattle, Washington

Recalled by: Manufacturer, by letter, March 4, 1982. Firm initiated recall See FDA press releases P82-4, February 18, 1982, P82-10, March 19, 1982 and FDA talk paper T82-15, March 5, 1982

Distribution: Washington State, Georgia, Iowa, South Carolina, England

Size & Quantity: 783 cases (48 cans/case) plus 41 cans were distributed in the United States and England

Reason: False double seams which could affect the integrity of the can and contents.

Product: Aleave brand Sterile Obstetrical Pads, 11 inch individually wrapped, used to disperse patient drainage, surgical dressing for prenatal care, post partum dressing, menstrual dressing, hemorrhoid dressing, and for D&C procedures, Recall #T-119-2

Code: All lots of catalog numbers 6510, 6520, 6512
Manufacturer: Beta Medical Products Company, Division Medical Disposable Company, Inc., East Brunswick, New Jersey
Recalled by: Manufacturer and Medical Disposable Company, Inc., Marietta, Georgia (parent company and distribution site), by telephone, February 25, 1982. Firm initiated recall
Distribution: New York, New Jersey, Connecticut, Pennsylvania, Maryland, Massachusetts, Maine, New Hampshire, Ohio, North Carolina, Florida, Texas, Georgia
Size & Quantity: 4187 cases/288 pads per case of catalog #6510; 183 cases/576 pads per case of catalog #6520; and 387 cases/288 pads per case of catalog #6512 were distributed
Reason: The sterility of the product is compromised due to defective seams.

Product: Dyonics 3.5 mm and 4.5 mm Intra-Articular Cutter Blade Assembly, an accessory of the Intra-Articular Surgical System, used to eliminate arthrotomy in orthopedic surgery in meniscal flap tear resection excision of plica and removal of cartilagenous loose bodies, Recall #T-120-2
Code: 3.5 mm blade assembly, part number 879-0295-12, serial numbers B167 thru B253; 4.5 mm blade assembly, part number 879-0296-12, serial numbers A412 thru A914
Manufacturer: Dyonics, Inc., Andover, Massachusetts
Recalled by: Manufacturer, by letter, January 18, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates 411 assemblies of both sizes remain on market
Reason: The assemblies have the potential to fracture and fragment during surgery.

Product: GX-550 "Galaxie", X-ray controls for radiographic or fluoroscopic use. These controls are in use daily, Recall #R-009-2
Code: Model 851 serials 501 - 1006, model 851A serials 1150 - 1311, model 851B serials 105 - 448
Manufacturer: Picker International, Highland Heights, Ohio
Recalled by: Manufacturer, by letter, November 30, 1981. Firm initiated field correction
Distribution: Nationwide and international
Size & Quantity: Firm estimates approximately 1109 units have been produced
Reason: Product is not in compliance with the entrance exposure rate requirements. These rates were significantly higher than the national average for noncompliant rates for entrance exposure.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Chocolate Condensed Pie, 33 ounces (2 pounds, 1 ounce) Recall #F-106-2
Code: F01232, G01232, H01232, J01232, K01232, L01232, M01232, N01232, P01232, Q01232, R01232
Manufacturer: Edwards Baking Company, Atlanta, Georgia
Recalled by: Manufacturer, by telephone, February 8, 1982. Firm initiated recall complete
Distribution: Southeast and Southwest United States
Size & Quantity: Firm estimates none remains on market
Reason: The firm found high plate counts and coliforms greater than 1000 per gram.

Seizure Actions Filed:

Product: Coco Rico Beverage (82-282-374)
Charge: Adulterated - Product contains an unsafe food additive (potassium nitrate)
Firm: Coco Rico, Inc., Naguabo, Puerto Rico
Filed: March 11, 1982 - U.S. District Court for the District of Puerto Rico at San Juan; Civil #82-0507, FDC #63673.

Product: Kokito Coconut (82-281-702)
Charge: Adulterated - Product contains an unsafe food additive (potassium nitrate)
Firm: Coco Rico, Inc., Naguabo, Puerto Rico
Filed: March 11, 1982 - U.S. District Court for the District of Puerto Rico at San Juan; Civil #82-0506, FDC #63674.

Product: Coco Rico Beverage (82-274-785)
Charge: Adulterated - Product contains an unsafe food additive (potassium nitrate)
Firm: Coco Rico, Inc., Naguabo, Puerto Rico
Filed: March 11, 1982 - U.S. District Court for the District of Puerto Rico at San Juan; Civil #82-0505, FDC #63675.

Product: "Beech-Nut 100% Fruit Juice Orange Juice From Concentrate *** Beech-Nut Foods ***"(82-345-790)
Charge: Adulterated - Turmeric has been added so as to make it appear better or of greater value
Firm: Fresh Pak Foods, Inc., McAllen, Texas
Filed: March 5, 1982 - U.S. District Court for the Northern District of California, at San Francisco; Civil #C-82-0914 WTS, FDC #63664.

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The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located

March 31, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Tolbutamide Tablets, USP, 0.5 g. in bottles of 100, 200, 500 and/or 1,000 tablets, an Rx drug used as an oral antidiabetes agent, to restore blood sugar to normal ranges, Recall #D-070-2
Code:	Lot numbers: B01408 EXP 5/85, A01568 EXP 6/85, A01448 EXP 5/85, F02818 EXP 11/85
Manufacturer:	Premo Pharmaceutical Labs,Inc., South Hackensack, New Jersey
Recalled by:	Lemmon Company, South Hackensack, New Jersey (formerly Premo Pharmaceutical Labs, Inc.), by letter under the Premo letterhead, March 1, 1982. Firm initiated recall
Distribution:	Nationwide
Size & Quantity:	Firm estimates very little or none remains on market
Reason:	Product fails to meet USP dissolution requirements.

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HE 20.4039:

Product: Melster Marshmallow Eggs - one dozen, 4 1/2 ounces in cardboard cases, Recall #F-113-2
Code: 2046/2049
Manufacturer: Melster Candies, Inc., Cambridge, Wisconsin
Recalled by: Manufacturer, by telephone, February 18-19, 1982. Firm initiated recall complete
Distribution: Kansas, Ohio, Michigan, Wisconsin
Size & Quantity: 1,222 cases were distributed
Reason: Possible salmonella contamination.

Product: Paul Corcellet Red Berries Freeze Dried, packaged in 3/4, 2/3, and 1 1/3 ounce jars, Recall #F-114-2
Code: Carton #'s 567, 576, 577 and all loose bottles (uncoded)
Manufacturer: Paul Corcellet, Paris, France (Importer: Europa Foods Ltd., Hauppauge, New York)
Recalled by: Jurgensen's Grocery Company, Pasadena, California, by telephone and memo, February 22, 1982. Firm initiated recall complete
Distribution: Southern California and San Francisco
Size & Quantity: Firm estimates none remains on market
Reason: Product contains the toxic berry schinus terebinthifolius.

Product: Pink Peppercorns, product is also known as "Baies Rose De Bourbon" an imported "exotic spice," packaged in 3 ounce and 8 ounce metal tins, Recall #F-115-2
Code: None
Manufacturer: The Spice Market, New York, New York
Recalled by: Manufacturer, by telephone and follow-up letters, February 19, 1982. Firm initiated recall
Distribution: New York
Size & Quantity: 127 oz. were distributed
Reason: Pink peppercorn is not an approved food additive.

Product: M/D2 and M/D2J Defibrillator Paddles - External Adult, #6910-00-0000, used with Datascope Defibrillator/Monitor, Models M/D2 and M/D2J. These devices are used by emergency service and emergency medical care personnel to defibrillate heart attack victims, Recall #T-039-2
Code: All serial numbers: Model M/D2, 1,001 through 3,528; Model M/D2J, 1,001 through 5,319
Manufacturer: Datascope Corporation, Paramus, New Jersey
Recalled by: Manufacturer, by notification letters dated September 2, 1981 for the M/D2J Defibrillator Paddles, and October 5, 1981 for the M/D2 Defibrillator Paddles, containing a test procedure to detect evidence of paddle switch contact wear. Only those paddles that fail to pass the test, or have been cleaned or lubricated in a certain manner must be replaced. Firm initiated recall
Distribution: Nationwide, Canada and international for use by hospitals (emergency rooms), first aid squads, rescue units, fire departments, and other emergency medical response teams and companies
Size & Quantity: Approximately 2,000 Model M/D2 and 4,000 Model M/D2J defibrillators are involved
Reason: Paddle switches may fail to deliver stored energy to patients due to increased switch resistance.

Product: Certain Cobe Heart/Lung Perfusion Sets that contain a specific plastic connector, and the connector itself which is also sold separately in bulk, Recall #T-122-2
Code: All lots
Manufacturer: Cobe Laboratories, Inc., Lakewood, Colorado (perfusion sets); Carl Newell Company, Glendale,California (plastic connector)
Recalled by: Cobe Laboratories, Inc., Lakewood, Colorado, by letter, March 2, 1982, with recommendation to visually inspect for leaks during priming and use. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: Firm estimates 9000 tubing sets and 93/50 connector cases remain on market
Reason: Leakage may occur at the tubing-to-connector attachment due to improper molding of the connector.

Product: Ohio Medical Modulus Anesthesia Gas Machine, Product #236-6232-910 Recall #T-125-2
Codes: Serial #'s ABLH00001 through ABLH00854 and Serial #'s ABLJ00001 through ABLJ00637
Manufacturer: Ohio Medical Products, Division of Airco, Inc., Madison, Wisconsin
Recalled by: Manufacturer, by letter, March 15-16, 1982, with instructions for inspecting the device. Firm initiated recall

Distribution: Nationwide and Canada
Size & Quantity: Approximately 1,400 units were distributed
Reason: The vaporizer selector valve control may not properly seat when turned clockwise to the right vaporizer position. This could result in an open gas circuit venting to the atmosphere and lead to insufficient anesthesizing.

Product: Albay Diluent for Allergenic Extract 4.5 ml., Normal Saline with Phenol, an Rx product used to prepare a desired concentration of allergenic extract, Recall #B-017-2
Code: Lot #0401, EXP date 9-84
Manufacturer: Hollister-Stier Laboratories, Inc., Division of Cutter Laboratories, Inc., Spokane, Washington
Recalled by: Manufacturer, by telephone, March 5, 1982. Firm initiated recall
Distribution: Nationwide, Canada and international
Size & Quantity: Firm estimates 5,000 to 10,000 vials remain on market
Reason: Approximately 20% of the vials comprising lot #0401 were incorrectly labeled as containing 9.0 ml. of diluent rather than the correct amount 4.5 ml.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Fleming brand S-P-T Thyroid Capsules, 2 grain; an Rx drug in translucent bottles of 100 and 1000, used for the treatment of inadequate endogenous thyroid productions, Recall #D-069-2
Code: "2020501" EXP 2/85
Manufacturer: R. P. Scherer North America, St. Petersburg, Florida
Recalled by: Fleming and Company, Fenton, Missouri (repacker), by letter dated February 11, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 104 bottles of 100's and 5 bottles of 1000's were distributed
Reason: Product is above USP limit for iodine content.

Product: Fiesta Brand Flat Fillets of Anchovies in 28 ounce cans, product of Morocco, Recall #F-110-2
Code: "E U /30 8 80"
Manufacturer: Unknown, Cadur Trading Corporation, Elizabeth, New Jersey (importer)
Recalled by: Vulpetti Cheese Distributors Inc., Hialeah, Florida, by letter, January 20, 1982. Firm initiated recall
Distribution: South Florida
Size & Quantity: 18 cases containing 12/28 ounce cans were distributed
Reason: Swollen cans.

NOTE:

Correction of July 8, 1981 Enforcement Report:

The seizure actions filed on June 2, 1981, against frozen confections at Marshall Confections, Inc., for adulteration with saccharin should have listed the product as "Popsie" brand frozen confection, not as "Popsicles." "Popsicle" is a trademark of Popsicle Industries.

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FDA Enforcement Report

Press Office
Food and Drug Administration
5600 Fishers Lane
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301/443-4177

The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions and recalls. The following is an explanation of these actions.

PROSECUTION: A criminal action filed by FDA against a company or individual charging violation of the law. Prosecutions listed below have been filed with a court but not yet tried or concluded.

SEIZURE: An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods until the matter is resolved. The date listed is the date a seizure request is filed, not the date of seizure.

INJUNCTION: A civil action filed by FDA against an individual or company seeking, in most cases, to stop a company from continuing to manufacture or distribute products that are in violation of the law. Injunctions listed have been filed with the court but not concluded.

RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

April 7, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	Polycillin-N (Sterile Ampicillin Sodium), Rx intramuscular or intravenous injection, 500 mg. and 1 gram vials, shrink wrapped in units of 10, Recall #D-073-2
Code:	500 mg. vials - lots K1M55, L1M01; 1 gram vials - lots L1M02; a portion of lot K1M55 was packaged under the Smith Kline and French label: SKF label lot #51106
Manufacturer:	Bristol Alpha Corporation, Barceloneta, Puerto Rico
Recalled by:	Bristol Laboratories, Division of Bristol-Myers Company, Syracuse, New York, by mailgram, March 9, 1982. Firm initiated recall
Distribution:	Nationwide, Puerto Rico, Guam, Panama, The Philippines
Size & Quantity:	Lot K1M55 - 184,100 vials includes 32,000 to SKF under lot #51106; lot L1M01 - 215,960 vials; lot L1M02 - 30,000 vials only to Puerto Rico were distributed. Firm estimates 25% remains on market
Reason:	Non-sterility.

Product: All canned salmon in 7.75 ounce size metal cans produced by the manufacturer/recalling firm in 1980 and 1981. The recall includes red, pink and chum species of salmon, various brands, Recall #F-111-2

Code: All codes produced in 1980 and 1981. The cans will have as the top line of a two-line code: R00 3, P00 3, C00 3, M00 3, K00 3, R01 3, P01 3, C01 3, M01 3, or K01 3

Manufacturer: Chugach Alaska Fisheries, Inc., Cordova, Alaska,

Recalled by: Chugach Alaska Fisheries, Inc., Seattle, Washington, by letter, March 12, 1982. Firm initiated recall. See FDA press releases P82-4 February 18, 1982; P82-10, March 19, 1982; P82-14, March 31, 1982 and FDA talk paper T82-15, March 5, 1982

Distribution: Nationwide, Canada, France, The Netherlands

Size & Quantity: A total of 3,045 cases (48 cans/case) and 63,215 cases (24 cans/case) plus 16 cans were distributed nationwide in 1980 and 1981. In addition, 29,926 cases (48 cans/case) and 2,800 cases (24 cans/case) were shipped internationally

Reason: Some of the cans may be defective which could affect the integrity of the product.

Product: All canned salmon in 7.75 ounce size metal cans produced by the manufacturer/recalling firm in 1980. Recall includes red, chum, and pink species of salmon, Recall #F-112-2

Code: All codes produced in 1980. In 1980 the firm stamped its cans with a star symbol as the second of five characters in the top line of a two-line code. The top line will begin R(star)OG, C(star)OG, P(star)OG, K(star)OG, or M(star)OG. The fifth character will be a number 1 through 4

Manufacturer: Diamond E. Fisheries, Inc., Egegik, Alaska

Recalled by: Diamond E. Fisheries, Inc., Seattle, Washington, by letter, March 12, 1982. Firm initiated recall. See FDA press releases P82-4, February 18, 1982; P82-10, March 19, 1982; P82-14, March 31, 1982 and FDA talk paper, T82-15, March 5, 1982

Distribution: Nationwide and international

Size & Quantity: 150,026 cases (48 cans/case) plus 29 cans were distributed

Reason: Some of the cans may be defective which could affect the integrity of the product.

Product: All canned salmon in 7.75 ounce size metal cans produced by the manufacturer/recalling firm in 1980 and 1981. The recall involves red, pink, coho and chum species of salmon. Various brand labels are involved, Recall #F-123-2

Code: All codes produced in 1980 and 1981. All codes will begin with one of the following: RGM, RGN, PGM, PGN, MGN, KGN, or CGN

Manufacturer: Petersburg Fisheries, Inc., Petersburg, Alaska

Recalled by: Petersburg Fisheries, Inc., Seattle, Washington, by letter, March 29, 1982. Firm initiated recall. See FDA press releases P82-4, February 18, 1982; P82-10, March 19, 1982; P82-14, March 31, 1982 and FDA talk paper, T82-15, March 5, 1982
Distribution: Nationwide and international
Size & Quantity: 281,310 cases, 48 cans/case, were distributed
Reason: Some of the cans may be defective which could affect the integrity of the product.

Product: All canned salmon in 7.75 ounce size metal cans produced by the manufacturer/recalling firm in 1980 and 1981. The recall involves red, pink, coho and chum species of salmon. Various brands labels are involved, Recall #F-124-2
Code: All codes produced in 1980 and 1981. Two coding systems are involved. Most cans will have a two-line code with five characters beginning with W in the top line. The letter W is followed by three numbers -- 152 through 274 -- and another letter: A, B, T, M, J, L, N, S, or K. Some of the early 1980 production had the letter W in the first position of the bottom line and the species (R, M, P or C) in the first position of the top line. On the top line, the species code is followed by one or three numbers and a letter. For example P9A/W---- or P205A/W----
Manufacturer: Wards Cove Packing Company, Inc., Ketchikan, Alaska
Recalled by: Manufacturer, by letter under the the letterhead of Frank B. Peterson Company, Seattle, Washington, March 26, 1982. Firm initiated recall. See FDA press releases P82-4, February 18, 1982; P82-10, March 19, 1982; P82-14, March 31, 1982 and FDA talk paper T82-15, March 5, 1982
Distribution: California, Michigan, New Jersey, New York, Pennsylvania, Washington State, Illinois, Minnesota, Wisconsin, Oregon, Massachusetts, Tennessee and international
Size & Quantity: Firm distributed 8,521 cases of reds, 1,390 cases of cohos, 48,239 cases of pinks, and 519 cases of chums (48 cans/case)
Reason: Some of the cans may be defective which could affect the integrity of the product.

Product: (a) Jumbo Pasteurized Crabmeat; (b) Special Pasteurized Crabmeat; (c) Backfin Pasteurized Crabmeat; (d) Cocktail Claw Pasteurized Crabmeat; (e) Claw Pasteurized Crabmeat in one pound metal cans, Recall #F-118/122-2
Code: All codes
Manufacturer: Old Dominion Crab Company, Inc., Newport News, Virginia
Recalled by: Manufacturer, by letters, February 11 and 23, 1982. Firm initiated recall complete
Distribution: Maryland, Pennsylvania, Ohio, Virginia
Size & Quantity: Firm estimates less than 1,000 cans were distributed
Reason: Swollen and leaking cans.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: (a) Scandia No. 461 Dual Action Cycler with Tension, a stationary exercise bicycle with tension control; (b) Scardia No. 462 Dual Action Cycler, Sears Model 2930 (private label), a stationary exercise bicycle, Recall #T-126/127-2

Code: There are no serial numbers. Products were distributed between August 1976 to August 1980

Manufacturer: Saw Mill River Industries, Inc., Yonkers, New York

Recalled by: Beacon Enterprises, Inc., Yonkers, New York (sales distributor), by press release jointly with the U.S. Consumer Product Safety Commission dated October 19, 1981. Firm initiated recall

Distribution: Nationwide, England, Sweden, Mexico

Size & Quantity: The Consumer Product Safety Commission estimates that 107,739 units remain in use

Reason: The labeling does not contain adequate directions for use or warnings. The labeling failed to alert the user to the potential risk of injury if the seat attachment bolt and nut are not assembled and secured properly.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: (a) Luride 1.0 mg. Brand of Sodium Fluoride LOZI-TABS, chewable tablets, assorted flavors in bottles of 120 tablets; (b) Luride 0.25 mg. Brand of Sodium Fluoride Quarter-strength LOZI-TABS, chewable tablets, vanilla flavored, in bottles of 120 tablets, used to prevent dental caries in children, Recall #D-071/072-2

Code: (a) Lot # 4261-2; (b) Lot # 4454-2

Manufacturer: ICN Pharmaceuticals Inc., Cincinnati, Ohio

Recalled by: Hoyt Laboratories, Norwood, Massachusetts, by letter, February 22, 1982. Firm initiated recall

Distribution: Nationwide, South Africa

Size & Quantity: (a) 9,804 bottles; (b) 60 bottles

Reason: Mislabeling. Some bottles of Luride 1.0 mg. are labeled as Luride 0.25 mg.

Product: Stokely-Van Camp's Finest California Fruit Cocktail in Heavy Syrup, 17 ounce cans, 24 cans per case, Recall #F-117-2

Code: 6FC23/G2502

Manufacturer: Pacific Coast Producers, Oraville, California

Recalled by: Stokely-Van Camp, Inc., Indianapolis, Indiana (distributor), by verbal authorization, November 19, 1981. Firm initiated recall complete

Distribution: Southeast Michigan
Size & Quantity: 7889 cases (24/12 ounce cans per case) were produced
Reason: Hydrogen swollen cans.

Product: Dona Maria Brand Mole En Pasta (a condiment) in 245 gram glass jars, Recall #F-116-2
Code: Not coded
Manufacturer: Productos Dona Maria, S.A., San Luis Potosi, S.L.P., Mexico
Recalled by: John Caperton, Dallas, Texas (food broker), by visit, February 19, 1982. Firm initiated recall complete
Distribution: Dallas and Arlington, Texas
Size & Quantity: 2843/245 gram jars were recovered from market
Reason: Insect adulteration.

Product: Sanko 70 kVp and 55 kVp dental X-ray systems, Recall #R-011-2
Code: 70 kVp system models W-70, W-1070, M-1070; 55 kVp system model W-55
Manufacturer: Sanko X-ray Manufacturing Company, Ltd. of Japan
Recalled by: Sanko Distributing Company, Ivor, Virginia (importer), by letter. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: 667 units were distributed
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968 in the following respects: The user's instruction does not clearly define basis of measurement for kVp, mA and time; and the timer setting deviated by more than the stated accuracy.

Seizure Actions Filed:

Product: "Extra Large Virginia Shelled Peanuts BIRDSONG PEANUTS Suffolk, Virginia ***" (82-390-846)
Charge: Adulterated - Product is contaminated with rodent urine and excreta pellets, and is rodent gnawed. Product also has been held under insanitary conditions whereby it may have become contaminated with filth
Firm: Art's Trading Company, San Francisco, California
Filed: March 15, 1982 - U.S. District Court for the Northern District of California at San Francisco; Civil #C-82-1048-AJZ, FDC #63679.

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FDA Enforcement Report

Press Office
Food and Drug Administration
5600 Fishers Lane
Rockville, Md. 20857
301/443-4177

The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

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INJUNCTION: A civil action filed by FDA against an individual or company seeking, in most cases, to stop a company from continuing to manufacture or distribute products that are in violation of the law. Injunctions listed have been filed with the court but not concluded.

RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

April 14, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	All canned salmon in 7.75 ounce size metal cans produced by the manufacturer in 1980 and 1981. The recall includes pink, red, coho and chum species of salmon. Various brand labels are involved, Recall #F-125-2
Code:	All codes produced in 1980 and 1981 at the Kodiak, Alaska plant. The cans have a two-line code with five characters in the top line. The codes will begin with HD13, HD14, RD13, RD14, MD13, MD14, CD13, or CD14. Example of top line code: HD13A
Manufacturer:	Whitney-Fidalgo Seafoods, Inc., Kodiak, Alaska
Recalled by:	Manufacturer, by letter, April 2, 1982. Firm initiated recall. See FDA press releases P82-4, February 18, 1982; P82-10, March 19, 1982; P82-14, March 31, 1982; P82-15, April 8, 1982 and FDA talk paper, T82-15, March 5, 1982
Distribution:	Nationwide and international
Size & Quantity:	410,847 cases (48 cans/case) were distributed
Reason:	Some of the cans may be defective which could affect the integrity of the product.

HE 20.4039:

Product: All canned salmon in 7.75 ounce size metal cans produced by the manufacturer/recalling firm in 1980 and 1981. The recall includes red, pink and chum species of salmon, various brands, Recall #F-111-2

Code: All codes produced in 1980 and 1981. The cans will have as the top line of a two-line code: R00 3, P00 3, C00 3, M00 3, K00 3, R01 3, P01 3, C01 3, M01 3, or K01 3

Manufacturer: Chugach Alaska Fisheries, Inc., Cordova, Alaska,

Recalled by: Chugach Alaska Fisheries, Inc., Seattle, Washington, by letter, March 12, 1982. Firm initiated recall. See FDA press releases P82-4 February 18, 1982; P82-10, March 19, 1982; P82-14, March 31, 1982 and FDA talk paper T82-15, March 5, 1982

Distribution: Nationwide, Canada, France, The Netherlands

Size & Quantity: A total of 3,045 cases (48 cans/case) and 63,215 cases (24 cans/case) plus 16 cans were distributed nationwide in 1980 and 1981. In addition, 29,926 cases (48 cans/case) and 2,800 cases (24 cans/case) were shipped internationally

Reason: Some of the cans may be defective which could affect the integrity of the product.

Product: All canned salmon in 7.75 ounce size metal cans produced by the manufacturer/recalling firm in 1980. Recall includes red, chum, and pink species of salmon, Recall #F-112-2

Code: All codes produced in 1980. In 1980 the firm stamped its cans with a star symbol as the second of five characters in the top line of a two-line code. The top line will begin R(star)OG, C(star)OG, P(star)OG, K(star)OG, or M(star)OG. The fifth character will be a number 1 through 4

Manufacturer: Diamond E. Fisheries, Inc., Egegik, Alaska

Recalled by: Diamond E. Fisheries, Inc., Seattle, Washington, by letter, March 12, 1982. Firm initiated recall. See FDA press releases P82-4, February 18, 1982; P82-10, March 19, 1982; P82-14, March 31, 1982 and FDA talk paper, T82-15, March 5, 1982

Distribution: Nationwide and international

Size & Quantity: 150,026 cases (48 cans/case) plus 29 cans were distributed

Reason: Some of the cans may be defective which could affect the integrity of the product.

Product: All canned salmon in 7.75 ounce size metal cans produced by the manufacturer/recalling firm in 1980 and 1981. The recall involves red, pink, coho and chum species of salmon. Various brand labels are involved, Recall #F-123-2

Code: All codes produced in 1980 and 1981. All codes will begin with one of the following: RGM, RGN, PGM, PGN, MGN, KGN, or CGN

Manufacturer: Petersburg Fisheries, Inc., Petersburg, Alaska

Recalled by: Petersburg Fisheries, Inc., Seattle, Washington, by letter, March 29, 1982. Firm initiated recall. See FDA press releases P82-4, February 18, 1982; P82-10, March 19, 1982; P82-14, March 31, 1982 and FDA talk paper, T82-15, March 5, 1982

Distribution: Nationwide and international

Size & Quantity: 281,310 cases, 48 cans/case, were distributed

Reason: Some of the cans may be defective which could affect the integrity of the product.

Product: All canned salmon in 7.75 ounce size metal cans produced by the manufacturer/recalling firm in 1980 and 1981. The recall involves red, pink, coho and chum species of salmon. Various brands labels are involved, Recall #F-124-2

Code: All codes produced in 1980 and 1981. Two coding systems are involved. Most cans will have a two-line code with five characters beginning with W in the top line. The letter W is followed by three numbers -- 152 through 274 -- and another letter: A, B, T, M, J, L, N, S, or K. Some of the early 1980 production had the letter W in the first position of the bottom line and the species (R, M, P or C) in the first position of the top line. On the top line, the species code is followed by one or three numbers and a letter. For example P9A/W---- or P205A/W----

Manufacturer: Wards Cove Packing Company, Inc., Ketchikan, Alaska

Recalled by: Manufacturer, by letter under the the letterhead of Frank B. Peterson Company, Seattle, Washington, March 26, 1982. Firm initiated recall. See FDA press releases P82-4, February 18, 1982; P82-10, March 19, 1982; P82-14, March 31, 1982 and FDA talk paper T82-15, March 5, 1982

Distribution: California, Michigan, New Jersey, New York, Pennsylvania, Washington State, Illinois, Minnesota, Wisconsin, Oregon, Massachusetts, Tennessee and international

Size & Quantity: Firm distributed 8,521 cases of reds, 1,390 cases of cohos, 48,239 cases of pinks, and 519 cases of chums (48 cans/case)

Reason: Some of the cans may be defective which could affect the integrity of the product.

Product: (a) Jumbo Pasteurized Crabmeat; (b) Special Pasteurized Crabmeat; (c) Backfin Pasteurized Crabmeat; (d) Cocktail Claw Pasteurized Crabmeat; (e) Claw Pasteurized Crabmeat in one pound metal cans, Recall #F-118/122-2

Code: All codes

Manufacturer: Old Dominion Crab Company, Inc., Newport News, Virginia

Recalled by: Manufacturer, by letters, February 11 and 23, 1982. Firm initiated recall complete

Distribution: Maryland, Pennsylvania, Ohio, Virginia

Size & Quantity: Firm estimates less than 1,000 cans were distributed

Reason: Swollen and leaking cans.

Size & Quantity: 444,150 bottles of the four lots were distributed
Reason: Superpotency due to evaporation of solution.

Product: Hawaii Tan Maker for Sun-Sensitive Skin, a sunscreening product packaged in 4 and 8 fluid ounce plastic bottles, Recall #D-075-2
Code: 1794 stamped in ink on bottom of container
Manufacturer: Fragrance Development Corporation, Chatsworth, California
Recalled by: C.M. Associates, Kaneohe, Hawaii, by visit, March 2, 1982. Firm initiated recall
Distribution: Hawaii
Size & Quantity: 34 cases of 12/4 ounce bottles and 40 cases of 12/8 ounce bottles remain in commerce
Reason: The product does not contain the active ingredient para-aminobenzoic acid (PABA) declared on the label.

Product: Island Spring Brand Tofu, 16 ounces, packaged in a plastic tray with a cellophane sealed top. Tofu is a soybean cake used in soups and vegetable dishes, an extension of Recall #F-072-2 which appeared on the February 24, 1982 Enforcement Report
Code: Extended to include any pull date prior to and including March 15, 1982. The code on the package would have been indicated as "Sell by MAR 15" or "3.15"
Manufacturer: Island Springs, Inc., Vashon, Washington
Recalled by: Manufacturer, by letter, March 22, 1982. Firm initiated recall
Distribution: Washington State, Oregon, Alaska, Idaho, Montana
Size & Quantity: Firm estimates none remains on market
Reason: Product is adulterated with Yersinia enterocolitica which causes yersinia intoxication or infection. The illness mimics appendicitis. The recall was requested by the Washington State Department of Agriculture on March 19, 1982 following investigation by FDA and the Washington State Department of Agriculture.

Product: (a) Four Pepperberries, a mixture of four different peppercorns, pink, green, black and white in 5 ounce packages; (b) "Pink Pepperberry Oil" in 12 fluid ounce bottles, Recall #F-127/128-2
Code: None
Manufacturer The Silver Palate, Inc., New York, New York (importer)
Recalled by: Importer, by letters, March 26, 1982. Firm initiated recall.
Distribution Nationwide and Canada
Size & Quantity: (a) 356 cases of 12/5 ounce packages; (b) 135 cases of 12/12 fluid ounce bottles

Reason: Product was found to consist of the fruits of *Schinus terebinthifolius*, which is not an approved food additive in the U.S. nor is it generally recognized as safe (GRAS).

Product: Quick Cooking (one minute) Rolled Oats in 18 ounce cylindrical boxes, 24 boxes per case, Recall #F-130-2
Code: Package code located on bottom of box: 2L22A3; case code: 1-22-2LB3
Manufacturer: The Quaker Oats Company, Cedar Rapids, Iowa
Recalled by: The Quaker Oats Company, Chicago, Illinois, by telephone with follow-up visits and letters, March 19, 1982. Firm initiated Recall
Distribution: Ohio and western New York
Size & Quantity: FDA estimates 500 cases remain on market
Reason: Some of the boxes of oats may contain pieces of a clear plastic tumbler.

Product: CPI Microthin-DI, Models 0520 and 0620-Demand Pulse Generators; CPI-Microthin PI, Models 0522 and 0622-Programmable Demand Pulse Generators; CPI-Microthin DII, Models 0521 and 0621-Demand Pulse Generators; and CPI Microthin PII, Models 0523 and 0623-Programmable Demand Pulse Generators. Models 0520, 0521, 0522 and 0523 are Unipolar and Models 0620, 0621, 0622 and 0623 are Bipolar, Recall #T-132/133-2
Code: Microthin DI and PI's (520/522) shipped prior to January 19, 1982 and all Microthin and P2's (521/523) built before January 1981. Serial number range (not all are inclusive): Model #520 - 144269/144307; Model #521 - 222496/225464; Model #522 - 143780/226349; Model #523 - 222531/225648; Model #620 - 140284/303317; Model #622 - 140337/142721; Model #623 - 222533/226097
Manufacturer: Cardiac Pacemakers, Inc., St. Paul, Minnesota
Recalled by: Manufacturer, by interoffice memo followed up by visits, January 21, 1981. Firm initiated recall complete
Distribution: Nationwide, Mexico, West Germany, Italy, Holland, Spain
Size & Quantity: Firm has provided for 98% accountability of all units involved
Reason: Some set screws packed with devices may be too short to make contact with the lead terminal pin in the connector block, resulting in failure to complete electrical circuit.

Product: (a) Whole Blood (Human); (b) Red Blood Cells (Human); (c) Red Blood Cells (Human), Washed; (d) Red Blood Cells (Human), Deglycerolized; (e) Single Donor Plasma (Human), Fresh Frozen; (f) Platelet Concentrate (Human); (g) Cryoprecipitate

Antihemophilic Factor (Human); (h) Recovered Human Plasma, an extension of Recall #B-009/016-2 which appeared on the March 17, 1982 Enforcement Report

Code: (a) 61T, 214T, 527J, 592J, 599K, 646R, 1356S, 2099J, 2242T, 2438S, 2522P, 2781T, 2859P, 3299R, 3474T, 3584T, 3990X, 4053X, 4129T, 4137T, 4212J, 4297J, 4520T, 4929X, 5172S, 5408X, 5418X, 6720F, 6930X, 7116C, 7488F, 8718H, 8973H; (b) 202T, 509J, 511J, 716Y, 905J, 1012Y, 1017R, 1193S, 1670K, 1986J, 2241F, 2481F, 2654K, 2720E, 2801P, 2878T, 2944E, 3294P, 3362S, 3551E, 4006J, 4014S, 4080J, 4197J, 4240E, 4517E, 4557H, 4575H, 4869X, 4887X, 4931X, 4940X, 4941X, 5452H, 5586S, 6343S, 6730S, 7054C, 7119C, 7215C, 7600F, 7605F, 9424P, 9431P; (c) 2192F, 4513E, 5131X; (d) none; (e) 509J, 511J, 716Y, 905J, 2481F, 2944E, 3551E, 4006J, 4080J, 4197J, 5131X, 5452H, 6343S, 6730S, 7054C, 7215C, 7600F, 7605F, 9424P, 9431P; (f) 509J, 511J, 543J, 716Y, 905J, 1670K, 2099J, 2481F, 2944E, 3551E, 4014S, 4080J, 4197J, 5131X, 5452H, 5586S, 6730S, 7215C, 7600F, 7605F, 9424P, 9431P; (g) 2720E, 3362S; (h) 3294P

Manufacturer: Belle Bonfils Memorial Blood Center, Denver, Colorado

Recalled by: Manufacturer, by letters dated March 26, 1982. Firm initiated recall

Distribution: Colorado, Kansas, Florida, New York, California

Size & Quantity: FDA estimates 5% of product is on the market. This does not include products that were further manufactured by the direct consignees of Belle Bonfils

Reason: Products were distributed which: (1) were presumptively reactive for hepatitis B surface antigen (HBsAg); (2) could not be correlated to specific results within a series where presumptive reactives were noted; or (3) were collected from a person found previously to have tested HBsAg reactives.

Product: Source Plasma (Human) - three units, intended for further manufacturing, Recall #B-018-2

Code: Identification numbers: 546779, 548434, 548013

Manufacturer: Plasma Services of San Antonio I, San Antonio, Texas

Recalled by. Plasma Services, Division of Blood Systems Inc., Scottsdale, Arizona, by telex, dated January 29, 1982 and February 1, 1982. Firm initiated recall

Distribution: Vienna, Austria and Frankfurt, Germany

Size & Quantity: Three units are involved

Reason: The units of Source Plasma (Human) tested reactive for hepatitis B surface antigen. These units were labeled as non-reactive and distributed.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Benzo Pinin Gotas, ear drops, Rx analgesic to relieve acute otitis pains, packed in 1/2 ounce plastic bottles, Recall #D-076-2
Code: Lot number 8E3912, code number 0190
Manufacturer: Dorasol Laboratories, Hato Rey, Puerto Rico
Recalled by: Manufacturer, by letters and visits beginning November [illegible], [illegible]. Firm initiated recall complete
Distribution: Puerto Rico
Size & Quantity: A total of 1,227 - 1/2 fluid ounce bottles were distributed
Reason: Discoloration due to reaction of product ingredients.

Product: Bonner Golden Raisins, 15 ounce cardboard box, Recall #F-131-2
Code: "153B1" embossed on lid
Manufacturer: Bonner Packing Company, Fresno, California
Recalled by: Purity Supreme Inc., Billerica, Massachusetts, by telex, January 29, 1982. Firm initiated recall
Distribution: Maine, Massachusetts, Connecticut, New Hampshire
Size & Quantity: Undetermined
Reason: Possible rodent contamination.

Product: Cott Tonic Water in 32 ounce clear glass bottles, Recall #F-132-2
Code: Carton code: 1-H-28; bottle code: None
Manufacturer: American Beverage Corporation, College Point, New York
Recalled by: Canada Dry Bottling Company of New York, College Point, New York, by visit, February 24, 1982. Firm initiated recall complete
Distribution: Massachusetts, Rhode Island, New Hampshire
Size & Quantity: 202 cases of 12/32 ounce bottles frozen at one distribution center
Reason: FDA samples revealed yeast contamination.

Product: Defibrinated Sheeps' Blood w/Alseaver's, used as a component in the preparation of sheep blood agar plates and slants, packaged in sterile glass bottles from 50 ml. to 200 ml., Recall #T-128-2
Code: Lot #'s B-0195-1 through B-0195-7 EXP Date 8/29/81
Manufacturer: Northeast Laboratory Services Inc., Winslow, Maine
Recalled by: Manufacturer, by telephone, August 19, 1981. Firm initiated recall complete
Distribution: Maine, New Hampshire

Size & Quantity: Firm estimates none remains on market
Reason: Mislabeled. "Sheep blood w/Alseavers" labeled as "Sheep Blood Defibrinated."

Product: Defibrinated Sheeps' Blood, used as a component in the preparation of sheep blood agar plates and slants, packaged in sterile glass bottles of uniform size but varying in net contents from 50 ml. to 100 ml., Recall #T-129-2
Code: Lot #B-0205-1 Through B-0205-7; EXP Date 9/11/81
Manufacturer: Northeast Laboratory Services Inc., Winslow, Maine
Recalled by: Manufacturer, by telephone, September 9, 1981. Firm initiated recall complete
Distribution: Maine, New Hampshire, Massachusetts
Size & Quantity: Firm estimates none remains on market
Reason: Product may be hemolyzed.

Product: "NEL 10" Chocolate Agar w/Enrichments an in-vitro diagnostic for the cultivation and isolation of N. Gonorrhoeae and N. Meningitides and Haemophilus, packaged in 100 x 15 mm. monoplates, Recall #T-130-2
Code: Lot # "596 EXP Date 4/1/82"
Manufacturer: Northeast Laboratory Services Inc., Winslow, Maine
Recalled by: Manufacturer, by telephone or visit, February 8, 1982. Firm initiated recall complete
Distribution: Maine
Size & Quantity: Firm estimates none remains on market
Reason: Product was contaminated with unidentified yellow colonies.

Seizure Actions Filed:

Product: Meclizine Hydrochloride Tablets (82-275-396)
Charge: Subpotent. Product was not manufactured in conformance with current Good Manufacturing Practices
Firm: Camall Company, Washington, Michigan
Filed: March 19, 1982 - U.S. District Court for the Western District of Kentucky at Bowling Green; Civil #C82-0031BG(s), FDC #63666.

Product: Mole (82-314-730)
Charge: Adulterated - Product contains insect fragments and rodent hairs. Misbranded - Labeling not in English language
Firm: Dona Maria S.A., Mexico
Filed: March 30, 1982 - U.S. District Court for the Northern District of Illinois, Eastern Division at Chicago; Civil #82C-1958, FDC #63680

Product: Mole (82-314-731)
Charge: Adulteration - Product contains insect fragments. Misbranded - Labeling not in English language
Firm: Dona Maria S.A., Mexico
Filed: March 30, 1982 - U.S. District Court for the Northern District of Illinois, Eastern Division at Chicago; Civil #82C-1957, FDC #63681.

Product: Candy products et al. (82-285-572 et al)
Charge: Adulterated - Products have been held under insanitary conditions whereby they may have become contaminated with filth, and consist in whole or in part of filth (rodent)
Firm: Shosho Brothers, Inc., Buffalo, New York
Filed: April 1, 1982 - U.S. District Court for the Western District of New York at Buffalo; Civil #82-298, FDC #63695.

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FDA Enforcement Report

Press Office
Food and Drug Administration

5600 Fishers Lane
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The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

PROSECUTION: A criminal action filed by FDA against a company or individual charging violation of the law. Prosecutions listed below have been filed with a court but not yet tried or concluded.

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April 21, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product: Isolated DC Defibrillator, Model #ISD-24, equipped with internal or pediatric paddles, #'s 979051, 979759, 979760 and 979054, used to restart the heart when some type of blockage occurs during surgery, Recall #T-123-2

Code: Internal defibrillator paddles (#979759), adult internal (#979051), infant internal (#979760) and infant/child external (#979054)

Manufacturer: Electronics for Medicine/Honeywell, Inc., Pleasantville, New York

Recalled by: Manufacturer, by letter, dated November 17, 1981, with instructions for inspecting device. Firm initiated recall complete

Distribution: United States and Canada

Size & Quantity: Firm estimates 460 defibrillators in commerce in the United States. The Canadian distribution is unknown

Reason: Possibility of defibrillator charging to full power while internal or pediatric paddles are in use. Jumper wire between pins in the connection can cause the defibrillator power not to be limited. Insulation on the jumper wire can be cut and the exposed wire can touch the connector housing defeating output and limiting circuit of defibrillator.

Class II - ***A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)***

Product: Furosemide Tablets, 20 mg., 100 tablet intermediate units, 24 units in a carton labeled as 20 mg., Rugby Brand, Recall #D-077-2

Code: H036G

HE 20.4039:

Manufacturer: Mylan Pharmaceuticals, Inc., Morgantown, West Virginia
Recalled by: Manufacturer, by letter, April 2, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 3600 units were distributed
Reason: A carton consisting of 24 bottles of 100 tablets, 20 mg. contained one bottle labeled 40 mg.

Product: Breyers Natural Vanilla Ice Cream with Natural Vanilla Beans in 1/2 gallon containers, Recall #F-137-2
Code: JUN 26 82 over M1233
Manufacturer: Kraft Dairy Group, Jacksonville, Florida
Recalled by: Manufacturer, by route truck pick-up, March 3-4, 1982. Firm initiated recall complete
Distribution: Southeast Florida and southeast Georgia
Size & Quantity: 7,800 1/2 gallon containers were distributed
Reason: Contaminated with ammonia.

Product: Simmons Olecranon Bone Screw in 2-3/8 inch and 2-3/4 inch sizes, Recall #T-135-2
Code: Product #YY7981-G487-01, batch #LOQ or YY7982-G487-02, batch #LOR, lot #EN58JSS
Manufacturer: Downs Surgical Ltd., Surrey, England
Recalled by: Downs Surgical, Inc., Decatur, Georgia, by letter, March 19, 1982. Firm initiated recall
Distribution: Florida, Georgia, Michigan, Missouri, Hawaii
Size & Quantity: 29 packages were distributed
Reason: Devices were packaged incorrectly. Item #YY7981, with a 2-3/8 inch screw, is packaged as Item #YY7982, with a 2-3/4 inch screw, and vice versa.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Chorionic Gonadotropin, USP, a bulk active ingredient powder used to formulate pregnancy test kits and an Rx injectable drug that stimulates male and female gonads to allow normal function, Recall #D-078-2
Code: Lot #93227
Manufacturer: The bulk powder manufactured by Diosynth B.V., OSS, Holland was later blended, repacked and relabeled by Organon, West Orange, New Jersey
Recalled by: Organon, Inc., West Orange, New Jersey, by telephone, March 30, 1982. Firm initiated recall complete
Distribution: One consignee in New Jersey
Size & Quantity: 20.80 grams (60 million units) in one bottle were distributed
Reason: The lot fails to meet USP requirements for loss on drying.

Product: Hydroxocobalamin Injection, 1000 mcg/ml., 10 and 30 ml. vials, used in the treatment of Megaloblastic anemia associated with a reduced ability to absorb vitamin B12 due to the absence of intrinsic factor Rx, Recall #D-079-2
Code: Lot #H861 and H958

Manufacturer: Lemmon Company, Rockville, Maryland
Recalled by: Manufacturer, by letter, March 30, 1982 followed up by telephone during week of April 12, 1982. Firm initiated recall
Distribution: Indiana, Pennsylvania, Michigan, Connecticut, California, Florida
Size & Quantity: 1000/10 ml. and 250/30 ml. vials of lot #H958 were distributed. Firm estimated 50% remain on market; 1700/30 ml. and 800/10 ml. vials of lot #H861 were distributed and the firm estimated 20% remains on market
Reason: Lack of assurance of stability within the expiration date.

Product: Foregger Anesthesia Machines Models: Compact 75, Foretrend, 100, Foretrend 300, and Foretrend 500, Recall #T-134-2
Code: Compact 75 serial #278-300; Foretrend 100 serial #4789, 4791, 4794, 4804, 4808, 4810, 4815-4818, 4823-4825, 4829-4839, 4849; Foretrend 300 serial #4781-4788, 4790, 4792, 4795-4798, 4800-4803, 4805-4807, 4809, 4811-4814, 4819-4822, 4727, 4728, 4842, 4843, 3-304; Foretrend 500 serial #203, 205-207, 216, 217, 224-226, 254-259, 275-283, 287-290, 292-296, 299-304, 310-312, 315-323, 327-328, 330, 370, 373, 374, 380, 409; one machine was built to customer's specifications
Manufacturer: Foregger Company, Inc., Smithtown, New York
Recalled by: Manufacturer, by letter, March 18, 1982. The device is to be retrofitted but not returned. Firm initiated recall
Distribution: Nationwide, Latin America, South America, Thailand
Size & Quantity: 180 units were distributed
Reason: The device may fail prematurely due to an oversize condition in the minor thread diameter of the valve nut stop.

Product: Nu-Trake Emergency Cricothyrotomy Device, intended only for use by physicians, for use in emergency cricothyrotomies, Recall #T-136-2
Code: Lot Nos. CT 2081, CT 6081, CT 7081
Manufacturer: Polamedico, Inc., Santa Monica, California
Recalled by: International Medical Device Inc., Canoga Park, California, by letters, January 25, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: Firm estimates 900 sets remain on market
Reason: The obturator supplied with the 8 mm airway tube may stick and be difficult to remove.

Seizure Actions Filed:

Product: Honey (81-219-988)
Charge: Adulterated - Glucose and/or corn syrup has been substituted wholly or in part for honey; Misbranded - Labels are false and misleading; labels violate the Fair Packaging and Labeling Act
Firm: J.H. Pilgrim, DeKalb, Mississippi
Filed: March 5, 1982 - U.S. District Court for the District of Nevada at Las Vegas; Civil #CV-LV'82-133-HEC, FDC #63578.

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April 28, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	Ventricular Inhibited Pulse Generator VVI, Model 1000, under the brand names of Valleylab and Synthemed, non-programmable demand pacemakers designed to be used with a unipolar lead. The units are intended to be implanted in the patient and have a life expectancy of 10 years with a unique "Reserve Cell" battery for back-up, Recall #T-121-2
Code:	All units are being recalled, all serial numbers would be between and including S10015 through S10305
Manufacturer:	Synthemed Corporation, Boulder, Colorado
Recalled by:	Manufacturer, by telephone and letter, December 23, 1981 and January 23, 1982. A third letter was to be sent April 23, 1982 to all consignees. Firm initiated recall
Distribution:	Colorado, Washington State, New York, Oregon, Vermont, Texas, California, Missouri, Japan, Austria
Size & Quantity:	108 units were distributed
Reason:	Units may be subject to unpredictable failure.

HE 20.4039:

Product: Bunn Model 65 Solid State Audio/Visual Ventilation Alarm System, designed to signal failure of time, pressure, volume or power when used in conjunction with any pressure or volume cycled ventilator, Recall #T-124-2
Code: Model #65. The device bears a serial number from 0001 to 0180 indicating the unit of production
Manufacturer: Greene and Kellogg, Inc., Bunn-Xorbox Division, Tonawanda, New York
Recalled by: Manufacturer, by letter, March 4, 1982 requesting return of product. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 162 units were distributed
Reason: A pressure switch component has a high failure rate.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Aerobic Eye Wash, OTC product indicated for eye wash and eye infections, in one fluid ounce glass bottles, Recall #D-080-2
Code: All codes
Manufacturer: Rozar, Inc., Garland, Texas
Recalled by: Vita Pro Products, Dallas, Texas, by letter dated April 6, 1982. Firm initiated recall
Distribution: California, Texas, Georgia, New York, Oregon, South Carolina, Washington, Wisconsin, Arizona, Florida, Pennsylvania, Alabama, Colorado, Idaho, Indiana, Louisiana, Maryland, New Jersey, North Carolina, North Dakota, Ohio, Tennessee, Illinois, West Virginia, Arkansas, Utah, Missouri, Australia
Size & Quantity: 526 units distributed between August 1, 1981 and April 1, 1982
Reason: Unapproved new drug and does not meet specifications of 21 CFR 200.50.

Product: "Vent-Lok Swivel Elbow Combination" and "Swivel Elbow Assembly," plastic, tubular, single use connectors used to connect patient tubing to mechanical respirators, for Rx use, Recall #T-131-2
Code: Combination-DHD 256A control #1362; Assembly-DHD 250A Control #1363
Manufacturer: Hubbard Industries, Division of Diemolding Corporation, Wampsville, New York
Recalled by: DHD Medical Products, Division of Diemolding Corporation, Canastota, New York, by telephone, February 22-23, 1982, and mailgrams, February 24, 1982. Firm initiated recall
Distribution: New York, California, Maryland, Texas, Illinois, Ohio, Massachusetts, Virginia, Kentucky, Pennsylvania, Florida, Michigan, Tennessee, Colorado, South Dakota, Minnesota, Utah, Wisconsin, Arkansas, Washington State, Canada
Size & Quantity: 22,020 units Swivel Elbow Combination and 1,051 units of Swivel Elbow Assembly were distributed
Reason: The units were improperly assembled causing them to become disconnected during use.

Product: (a) Pink Berries prepared with Vinegar packed in 1.41 ounce, 2.82 ounce and 4.58 ounce glass jars under the ETS Moulin label; (b) Red Berries Freezer Dried, packed in 1-1/3 ounce and 6 ounce glass jars under the Paul Corcellet label, Recall #F-138/139-2

Code: Not coded

Manufacturer: (a) ETS Moulin, S.A., St. Maur Des Foss; (b) Paul Corcellet of France, Paris, France

Recalled by: Europa Food Ltd., Hauppauge, New York, by letter, April 6, 1982. Firm initiated recall

Distribution: Nationwide

Size & Quantity: (a) 192 cartons containing 12 jars each were distributed; (b) 409 cartons containing 12 jars each were distributed

Reason: Products contain Schinus terebinthifolius which is not an approved food additive in the United States nor is it generally recognized as safe (GRAS).

Product: Unlabeled Mahi Mahi fish fillets, product of Panama, Recall #F-140-2

Code: Uncoded

Manufacturer: Pan American Seafood, Inc. (importer), Fairfield, New Jersey

Recalled by: O'Neil and Hoffner Fisheries, Inc. (distributor), Detroit, Michigan, by telephone, March 26, 1982. Firm initiated recall complete

Distribution: Michigan, Ohio

Size & Quantity: Approximately 100 pounds remain on market

Reason: Food illness complaints after eating product which was found to contain high histamine levels.

Product: Mountain Dew, 16 ounce returnable glass bottles, citrus flavored carbonated soft drinks, Recall #F-142-2

Code: GCC on bottle cap; all products manufactured prior to April 9, 1982

Manufacturer: Pepsi-Cola Bottlers of Dayton, Dayton, Ohio

Recalled by: Manufacturer (franchised by G.C.C. Beverages, Inc.), by telephone, April 9, 1982. Firm initiated recall

Distribution: Ohio

Size & Quantity: Approximately 866,000 bottles were produced between March 4, 1982 through April 6, 1982.

Reason: Contaminated with sodium hydroxide.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Topmost brand Tiny Whole Beets in 8 1/4 ounce cans, Recall #F-141-2

Code: BTB10 over 19281, BTB10 over 29281, BTB1? (last number unreadable) over 20273

Manufacturer: Aunt Nellies Foods, Inc., Clyman, Wisconsin

Recalled by: General Grocer Company, St. Louis, Missouri, by bulletin, March 9, 1982. Firm initiated recall complete

Distribution: Missouri, Illinois

Size & Quantity: Firm estimates none remains on market

Reason: Swollen cans.

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Code:	All units are being recalled, all serial numbers would be between and including S10015 through S10305
Manufacturer:	Synthemed Corporation, Boulder, Colorado
Recalled by:	Manufacturer, by telephone and letter, December 23, 1981 and January 23, 1982. A third letter was to be sent April 23, 1982 to all consignees. Firm initiated recall
Distribution:	Colorado, Washington State, New York, Oregon, Vermont, Texas, California, Missouri, Japan, Austria
Size & Quantity:	108 units were distributed
Reason:	Units may be subject to unpredictable failure.

HE 20.4039:

Product: Bunn Model 65 Solid State Audio/Visual Ventilation Alarm System, designed to signal failure of time, pressure, volume or power when used in conjunction with any pressure or volume cycled ventilator, Recall #T-124-2

Code: Model #65. The device bears a serial number from 0001 to 0180 indicating the unit of production

Manufacturer: Greene and Kellogg, Inc., Bunn-Xorbox Division, Tonawanda, New York

Recalled by: Manufacturer, by letter, March 4, 1982 requesting return of product. Firm initiated recall

Distribution: Nationwide

Size & Quantity: 162 units were distributed

Reason: A pressure switch component has a high failure rate.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Aerobic Eye Wash, OTC product indicated for eye wash and eye infections, in one fluid ounce glass bottles, Recall #D-080-2

Code: All codes

Manufacturer: Rozar, Inc., Garland, Texas

Recalled by: Vita Pro Products, Dallas, Texas, by letter dated April 6, 1982. Firm initiated recall

Distribution: California, Texas, Georgia, New York, Oregon, South Carolina, Washington, Wisconsin, Arizona, Florida, Pennsylvania, Alabama, Colorado, Idaho, Indiana, Louisiana, Maryland, New Jersey, North Carolina, North Dakota, Ohio, Tennessee, Illinois, West Virginia, Arkansas, Utah, Missouri, Australia

Size & Quantity: 526 units distributed between August 1, 1981 and April 1, 1982

Reason: Unapproved new drug and does not meet specifications of 21 CFR 200.50.

Product: "Vent-Lok Swivel Elbow Combination" and "Swivel Elbow Assembly," plastic, tubular, single use connectors used to connect patient tubing to mechanical respirators, for Rx use, Recall #T-131-2

Code: Combination-DHD 256A control #1362; Assembly-DHD 250A Control #1363

Manufacturer: Hubbard Industries, Division of Diemolding Corporation, Wampsville, New York

Recalled by: DHD Medical Products, Division of Diemolding Corporation, Canastota, New York, by telephone, February 22-23, 1982, and mailgrams, February 24, 1982. Firm initiated recall

Distribution: New York, California, Maryland, Texas, Illinois, Ohio, Massachusetts, Virginia, Kentucky, Pennsylvania, Florida, Michigan, Tennessee, Colorado, South Dakota, Minnesota, Utah, Wisconsin, Arkansas, Washington State, Canada

Size & Quantity: 22,020 units Swivel Elbow Combination and 1,051 units of Swivel Elbow Assembly were distributed

Reason: The units were improperly assembled causing them to become disconnected during use.

Product: (a) Pink Berries prepared with Vinegar packed in 1.41 ounce, 2.82 ounce and 4.58 ounce glass jars under the ETS Moulin label; (b) Red Berries Freezer Dried, packed in 1-1/3 ounce and 6 ounce glass jars under the Paul Corcellet label, Recall #F-138/139-2
Code: Not coded
Manufacturer: (a) ETS Moulin, S.A., St. Maur Des Foss; (b) Paul Corcellet of France, Paris, France
Recalled by: Europa Food Ltd., Hauppauge, New York, by letter, April 6, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: (a) 192 cartons containing 12 jars each were distributed; (b) 409 cartons containing 12 jars each were distributed
Reason: Products contain Schinus terebinthifolius which is not an approved food additive in the United States nor is it generally recognized as safe (GRAS).

Product: Unlabeled Mahi Mahi fish fillets, product of Panama, Recall #F-140-2
Code: Uncoded
Manufacturer: Pan American Seafood, Inc. (importer), Fairfield, New Jersey
Recalled by: O'Neil and Hoffner Fisheries, Inc. (distributor), Detroit, Michigan, by telephone, March 26, 1982. Firm initiated recall complete
Distribution: Michigan, Ohio
Size & Quantity: Approximately 100 pounds remain on market
Reason: Food illness complaints after eating product which was found to contain high histamine levels.

Product: Mountain Dew, 16 ounce returnable glass bottles, citrus flavored carbonated soft drinks, Recall #F-142-2
Code: GCC on bottle cap; all products manufactured prior to April 9, 1982
Manufacturer: Pepsi-Cola Bottlers of Dayton, Dayton, Ohio
Recalled by: Manufacturer (franchised by G.C.C. Beverages, Inc.), by telephone, April 9, 1982. Firm initiated recall
Distribution: Ohio
Size & Quantity: Approximately 866,000 bottles were produced between March 4, 1982 through April 6, 1982.
Reason: Contaminated with sodium hydroxide.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Topmost brand Tiny Whole Beets in 8 1/4 ounce cans, Recall #F-141-2
Code: BTB10 over 19281, BTB10 over 29281, BTB1? (last number unreadable) over 20273
Manufacturer: Aunt Nellies Foods, Inc., Clyman, Wisconsin
Recalled by: General Grocer Company, St. Louis, Missouri, by bulletin, March 9, 1982. Firm initiated recall complete
Distribution: Missouri, Illinois
Size & Quantity: Firm estimates none remains on market
Reason: Swollen cans.

Complaints For Injunction Filed:

Against: Midwest Biologicals, Inc., Fenton, Michigan and Melvin R. Shultz, President and Treasurer
Product: In-Vitro Diagnostics (DOC 81-186-918, et al.)
Charge: Adulterated - Products are not manufactured in conformity with applicable Good Manufacturing Practice regulations; products are not of adequate purity; Misbranded - Labeling lacks adequate directions for use; labels bear expiration dates that are false and misleading since the devices are not useful for the period of time represented by those expiration dates
Filed: April 16, 1982 - U.S. District Court for the Eastern District of Michigan, Southern Division at Flint; Civil #82-40142, INJ #998.

Seizure Actions Filed:

Product: Rice (82-274-792)
Charge: Adulterated - Product contains insects and processed under insanitary conditions
Firm: Rice Growers of California (P.R.) Inc., Guaynabo, Puerto Rico
Filed: April 8, 1982 - U.S. District Court for the District of Puerto Rico; Civil #82-0859, FDC #63701

Note:

Recall #T-132/133-2, which appeared in the Enforcement Report of April 14, 1982, should be corrected to read as follows: "Code: Microthin DI and PI's (520/522) shipped prior to January 19, 1981. . ."

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FDA Enforcement Report

Press Office
Food and Drug Administration

5600 Fishers Lane
Rockville, Md. 20857

301/443-4177

The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

PROSECUTION: A criminal action filed by FDA against a company or individual charging violation of the law. Prosecutions listed below have been filed with a court but not yet tried or concluded.

SEIZURE: An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods until the matter is resolved. The date listed is the date a seizure request is filed, not the date of seizure.

INJUNCTION: A civil action filed by FDA against an individual or company seeking, in most cases, to stop a company from continuing to manufacture or distribute products that are in violation of the law. Injunctions listed have been filed with the court but not concluded.

RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

Recalls and Field Corrections:

May 5, 1982

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	(a) Island Mix - shipped prior to March 1, 1982, in 1-3/4 ounce jars; (b) Pink Pepper Mustard in 7-1/2 ounce jars, Recall #F-143/144-2
Code:	Not coded
Manufacturer:	Paul Corcellet of France, Paris, France
Recalled by:	Europa Food Ltd., Hauppauge, New York (importer), by letter, April 6, 1982. Firm initiated recall
Distribution:	Nationwide
Size & Quantity:	(a) 162 cases (12 jars/case); (b) 45 cases (12 jars/case) were distributed
Reason:	Products contain Schinus terebinthifolius which is not an approved food additive in the United States nor is it generally recognized as safe (GRAS).

HE 20.4039:

Product: (a) Stayfresh brand Homogenized UHT Milk Vitamin A & D added; (b) Stayfresh brand Homogenized Chocolate Lowfat UHT Milk; (c) Stayfresh brand 2% Lowfat UHT Milk in 33.8 fluid ounce (one liter) foil-lined paper cartons, Recall #F-146/148-2

Code: Products with pull dates 10-22-81, 3-15-82, 3-16-82, 3-17-82, 3-26-82, 4-15-82, 4-22-82, 4-28-82, 5-9-82, 5-15-82, 5-17-82, 9-23-82, 10-6-82

Manufacturer: Valley Fresh Products, Inc., Sumner, Washington

Recalled by: Manufacturer, by letter, April 8 and 22, 1982. Firm initiated recall

Distribution: Washington State, Alaska, Idaho, Pennsylvania, Oregon, California, Pago Pago, American Samoa and Caracas, Venezuela

Size & Quantity: Approximately 10,000 cases (12/33.8 fluid ounce cartons/case) were distributed

Reason: Products do not meet criteria for commercial sterility.

Product: Surgitek Mammary Implants, Low Volume, Round, Bi-Lumen Quin-seal Valve, sizes 255/265, 255/290, 285/320, 285/325, 320/365, 365/415, 440/500, 485/550, 265/305, and 330/370, Recall #T-137-2

Code: All codes manufactured since June 29, 1981.

Manufacturer: Medical Engineering Corporation, Racine, Wisconsin

Recalled by: Manufacturer, by telephone, March 31, 1982. Firm initiated recall

Distribution: Nationwide, Canada, England, Austria, France, New Zealand, Israel, Norway, Australia, South Africa

Size & Quantity: 984 packages were distributed

Reason: Some lid seals on the packaging bowls have a void which may compromise the sterility of the device.

Product: Quantum Pulse Generators, multi-programmable pacers, Recall #T-138-2

Code: Model #'s 253-09 (Unipolar); 254-09 (Bipolar); 254-10 (Bipolar/inline coaxial), serial #'s 1000, 1003*, 1004*, 1005*, 1006*, 1007*, 1008, 1009*, 1012*, 1013*, 1016, 1017, 1018*, 1022, 1023*, 1024*, 1025*, 1027*, 1028*, 1029*, 1031*, 1034*, 1037*, 1039*, 1040*, 1041*, 1042*, 1046*, 1047, 1049*, 1051*, 1052*, 1053, 1054*, 1056, 1057, 1058, 1069, 1070, 1071, 1072*, 1073*, 1074*, 1075, 1078*, 1082, 1088*, 1090, 1093, 1094*, 1095, 1096*, 1097*, 1099*, 1102*, 1106*, 1107, 1108, 1110, 1111, 1112, 1113*, 1118, 1122, 1126*, 1127, 1128*, 1129, 1132*, 1133, 1135*, 1136, 1137, 1142, 1143, 1145, 1146, 1147, 1152, 1153, 1154, 1156*, 1158, 1159, 1160, 1161*. *Denotes units implanted without modification. Where there is no asterisk, the unit was returned to the manufacturer for modification.

Manufacturer: Intermedics, Inc., Freeport, Texas

Recalled by: Manufacturer, verbally, on or about February 5, 1982. Firm initiated recall complete

Distribution: Nationwide

Size & Quantity: 86 pacers are subject to recall

Reason: Some pacers programmed for the maximum 120 ppm (pulse per minute) rate and programmed at the maximum pulse width and at the maximum pulse amplitude may revert to 70/72 ppm. This condition was corrected by replacing a resistor.

Product: (a) Platelet Concentrate (Human) [outdated for further manufacturing use]; (b) Recovered Human Plasma, an extension of Recall #B-014-2 and B-016-2 which orginally appeared on the March 17, 1982 Enforcement Report

Code: (a) 1636S, 3120X, 3121X, 3122X, 3126X, 3127X, 3129X, 3136X, 3137X, 3138X, 3188J, 3190J, 3191J, 3192J, 3198J, 3200J, 3205J, 3208J, 3210J, 3213J, 9351F, 9359F, 9360F, 9365F, 9369F, 9370F, 9375F, 9377F, 9378F, 9379F, 9382F, 3730S, 4006J, 4968S, 6596X, 7054C; (b) 1614S, 1630S, 1632S, 1636S, 1693X, 1702X, 1707X, 1719X, 2208T, 2209T, 2210T, 2214T, 2220T, 2222T, 2229T, 2230T, 2233T, 2234T, 2237T, 2244T, 2245T, 2248T, 2250T, 2252T, 2254T, 2256T, 2258T, 2259T, 3121X, 3139X, 3140X, 3142X, 3149X, 3153X, 3154X, 3159X, 3164X, 3165X, 3167X, 3168X, 3151P, 3153P, 3154P, 3155P, 3156P, 3159P, 3163P, 3186J, 3188J, 3191J, 3193J, 3203J, 3204J, 3209J, 3210J, 3214J, 3215J, 3217J, 3220J, 3222J, 3223J, 3226J, 3228J, 3229J, 3231J, 3232J, 3234J, 3235J, 3237J, 3239J, 3240J, 3241J, 3242J, 3244J, 3248J, 3249J, 3251J, 3252J, 3254J, 3257J, 3259J, 3265J, 3267J, 3271J, 3274J, 3278J, 3280J, 3286J, 4263J, 4264J, 4265J, 4267J, 4268J, 4271J, 6815X, 9382F, 9383F, 9392F, 9393F, 9398F, 9399F, 9401F, 9403F, 9404F, 9405F, 9406F, 9409F, 9410F, 9411F, 9412F, 9419F, 9422F, 9423F, 9425F, 9428F, 9430F, 9431F, 9432F, 9434F, 9436F, 9437F, 9441F, 9446F, 9449F, 9450F, 9451F, 9452F, 9453F, 9464F, 9467F, 9469F, 9470F, 9472F, 9474F, 9480F, 9486F, 9487F, 9489F, 9490F, 9491F, 9493F, 9494F, 9502F, 9503F, 9514F, 9516F, 202T, 674Y, 1012Y, 1017R, 1193S, 1617X, 1986J, 2192F, 2241F, 2720E, 2801P, 3362S, 3393X, 3730S, 3865S, 4240E, 4513E, 4517E, 4610X, 4637X, 4873F, 5347V, 6596X, 7119C, 8669X

Manufacturer: Belle Bonfils Memorial Blood Center, Denver, Colorado

Recalled by: Manufacturer, by letter, April 14, 1982. Firm initiated recall

Distribution: Florida, California, Illinois, New York, Italy

Size & Quantity: Undetermined

Reason: Products were distributed which: (1) were presumptively reactive for hepatitis B surface antigen (HBsAg); (2) could not be correlated to specific results within a series where presumptive reactives were noted; or (3) were collected from persons found to have previously tested HBsAg reactive.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Psora-Caps (Methoxsalen USP), 10 mg., psoriasis treatment, an Rx drug in 100 capsule bottles, an extension to the retail level of Recall #D-064-2 which appeared on the February 24, 1982 Enforcement Report
Code: Lot #50719
Manufacturer: Cord Laboratories, Inc., Broomfield, Colorado
Recalled by: Manufacturer, by letter, March 26, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 4,471/100 capsule bottles were distributed
Reason: Product being marketed without an approved New Drug Application.

Product: Watkins Supercold Cough Medicine with D-Methorphan Antitussive in six fluid ounce glass bottles, Recall #D-081-2
Code: 41337, 41336, 40898, 40897
Manufacturer: Watkins Incorporated, Winona, Minnesota
Recalled by: Manufacturer, by letter, April 2, 1982. Firm initiated recall
Distribution: Unknown
Size & Quantity: 25,476 six ounce bottles were distributed
Reason: Product may be contaminated with osmophilic yeast which may result in breaking bottles.

Product: Julina Brand Ground Clove, used mainly to flavor homemade Portuguese sausage, repacked into 1/2 ounce glass bottles, Recall #F-145-2
Code: Not coded
Manufacturer: Julina Imports, Inc., Chicopee, Massachusetts (repacker)
Recalled by: Repacker, by visit, March 18, 1982. Firm initiated recall complete
Distribution: Massachusetts, Connecticut, Rhode Island
Size & Quantity: Firm estimates 10 cases (24 bottles/case) remain on market
Reason: Short weight due to incorrect net weight statement on label.

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FDA Enforcement Report

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May 12, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	(a) Combinal Dye for the Eyebrows and Eyelashes - Black; (b) Combinal Dye for the Eyebrows and Eyelashes - Brown; (c) Combinal Dye for the Eyebrows and Eyelashes - Blue, in 0.25 ounce tubes, Recall #F-149/151-2
Code:	All lots
Manufacturer:	W. Pauli, Vienna, Austria
Recalled by:	Lon Cosmetics Ltd., Brooklyn, New York (importer/distributor), by letter, April 16, 1982. Firm initiated recall. See FDA press release P82-16, April 9, 1982
Distribution:	Nationwide
Size & Quantity:	555 tubes have been distributed since November 1981. Firm estimates less than 50% remains on market
Reason:	Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

Product:	Revital products in powder and gel form. The powder is in a 4 ounce plastic container. The gel is in a 55 gram tube. Both products are used primarily for healing open wounds, Recall #T-145/146-2

HE 20. 4039:

Code: All products (no code on labels)
Manufacturer: Robertson Resources, Ltd., Salisbury, Maryland
Recalled by: Manufacturer, by telephone and letter, April 21, 1982. Firm initiated recall. See FDA talk paper T82-30, April 29, 1982
Distribution: Nationwide
Size & Quantity: Unknown
Reason: FDA tests have found the products to be contaminated with known human pathogens.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Bristol-Myers 4 Way Long Acting Nasal Spray Decongestant 1/2 ounce squeeze bottle, an OTC drug that provides temporary relief of nasal congestion due to the common cold, sinusitis, hay fever or other respiratory allergies, Recall #D-082-2
Code: L2A103, L2A104
Manufacturer: Bristol-Myers Products, Ladue, Missouri
Recalled by: Bristol-Myers Products, Hillside, New Jersey, by telephone, April 15, 1982 and letter, April 28, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 319 cases 36 bottles each of L2A103 and 538 cases, 36 bottles each of L2A104 were distributed
Reason: Mislabeled - The front label on the bottle indicates that it is 4 Way Long Acting Nasal Spray, which it is. The rear label on the bottle is for 4 Way Mentholated Nasal Spray, which states incorrect dosages.

Product: Various Candies: (a) Starlight Mints (individually wrapped peppermint), 14 ounces; (b) Large Peppermint (pillow shaped mints), 9 ounces; (c) Gloria Mix (holiday mix assorted hard Christmas candies), 11 ounces; (d) Arabian Nights (assorted hard Christmas candies with design in center) 14 ounces; (e) Candy Peanuts (peanut shaped candy) 14 ounces; (f) Christmas Cherries, 14 ounces; (g) Jelly Beans (jelly bellies), 14 ounces, packed in clear glass canisters with decorative tops, Recall #F-152/158-2
Code: None
Manufacturer: E.J. Bracks & Sons, Inc., Chicago, Illinois
Recalled by: It's The Tops by Dorsey, Southfield, Michigan (repacker), by telephone, the first week of January 1982. Firm initiated recall complete
Distribution: Michigan, Ohio

Size & Quantity: (a) 5 dozen; (b) 5 dozen; (c) 5 dozen; (d) 11 dozen; (e) 11 dozen; (f) 11 dozen; (g) 6 dozen canisters were distributed
Reason: Chemical contamination

Product: Geisha Brand Albacore Solid White Tuna in Water, in 10 ounce cans, Recall #F-160-2
Code: H21A6 H21B6
841N1 841N1
Manufacturer: Neptune Packing Corporation, Mayaguez, Puerto Rico (packer)
Recalled by: Nozaki America, Inc., New York, New York, by visits, April 5, 1982 and letters, April 14, 1982. Firm initiated recall
Distribution: New England area
Size & Quantity: Firm estimates 2,192 cases remain on market
Reason: An odor and taste of lubricating (machine) oil in the product.

Product: Simmons (Thonet) Brand Pediatric Cribs; chrome plated frame and stainless steel frame; sizes: 27"x42"; 30"x54"; 36"x60"; 36"x72"; 29"x54"x61", 35"x60"x61" and 35"x72"x61", Recall #T-139-2
Code: PHC model numbers (manufactured 1976-1977): PHC 240D-101-LC209-1, PHC-240D-102-LC-209-2, PHC-240D-103-LC-209-3, PHC-240D-105-LC-209-5, PHC-241D-102-ULC17-2, PHC-241D-103-ULC17-3; 12 models (manufactured 1977-present): 121.550, 123.551, 125.552; 13 models (manufactured 1980-present): 131.550, 133.551, 135.552
Manufacturer: Gulf and Western Healthcare, Inc., Charlotte, North Carolina
Recalled by: Manufacturer, by letter, April 5, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Approximately 1,000 cribs were distributed
Reason: Missing spacers between the top and the bottom section of the crib resulted in the locking mechanism of the movable section of the crib top to not operate properly by not engaging. Users are to examine the crib for missing spacers.

Product: Multi-Programmable Pacers Model 5976 Bipolar and Model 5977 Unipolar, SX-HT High Threshold Pacemaker, Recall #T-140/141-2
Code: All serial numbers
Manufacturer: Medtronic, Inc., Minneapolis, Minnesota
Recalled by: Manufacturer, by letter dated March 10, 1982 to physicians and firm's sales force. Physicians were advised to review each patient's condition to determine whether a potential for undersensing exists. Firm initiated recall
Distribution: Nationwide, Canada and international
Size & Quantity: 300 units nationwide and 127 units internationally were distributed

Reason: Units have the potential for exhibiting undersensing or no sensing under specific conditions.

Product: Certain Olson Heart/Lung Perfusion sets that contain a Cobe 3/8" - 1/2" Reducer Connector component, used as a joint to connect different size tubing while the set is used during heart/lung surgery, Recall #T-142-2

Code: Connector lot #014341111 in Perfusion Sets under lot numbers 7027, 7071, 7076, 7090, 8000, 8033, 8006/8, 8010, 8018, 8021, 8026, 8030, 8037, 8039, 8049, 8054, 8061, 8062, 8072

Manufacturer: Carl Newell Company, Glendale, California

Recalled by: Olson Medical Sales Inc., Ashland, Massachusetts, by telephone, March 2, 1982 with follow-up letters sent between March 12 and 23, 1982 containing instructions to test the device for leaks and, if found, how to correct them. Firm initiated recall

Distribution: Virginia, Massachusetts, California, Arkansas, Illinois, New York, South Carolina and Washington, D.C.

Size & Quantity: Firm estimates 426 sets with the connector as a component remain on market

Reason: Leakage may occur at the tubing-to-connector attachment due to improper molding of the connector.

Product: Bear 2 Adult Volume Ventilator, a multimodal volume ventilator used to provide respiratory support to both ventilator dependent and non-ventilator dependent patients, Recall #T-143-2

Code: Serial #'s 1002 - 1780

Manufacturer: Bear Medical Systems, Inc., Riverside, California

Recalled by: Manufacturer, by mailgrams and notices, March 12, 1982. Firm initiated field correction

Distribution: Nationwide and international

Size & Quantity: 637 units were distributed

Reason: Defect in product which allows an extreme negative pressure to be applied to the patient.

Product: General purpose TEA-CO2 lasers used in research and high power industrial applications, Recall #R-013-2

Code: Models DD-250 and DD-300, manufactured and sold during 1977 and 1978

Manufacturer: Gen-Tec, Inc., Quebec, Canada

Recalled by: FDA approved the firm's corrective action program April 6, 1982. Firm initiated field correction

Distribution: California, Louisiana, New York, Utah, Wisconsin, New Mexico

Size & Quantity: Eight units have been introduced into commerce

Reason: Noncompliance with FDA Performance Standard under the Radiation Control for Health and Safety Act of 1968 in that

(1) the remote control connector does not conform to the requirement of the standard, (2) the word "invisible" is not included on logotype and aperture labels, (3) the user and service manuals do not include reproduction and location of warning labels, (4) the logotype was not included in sales literature, and (5) one special unit, Model DD-300-SLM, does not conform to the requirement of the standard for a safety interlock.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Generic Label Peanut Butter, 18 ounce glass jars, 12 jars/case, creamy and chunky, Recall #F-161/162-2
Code: Creamy Style jars: "DEC 11 82," cases "21345"; Chunky Style jars: "DEC 10 82," cases: "21344"; jars: "DEC 8 82," cases "11342"; jars: "DEC 7 82," cases "34112"
Manufacturer: Portales Valley Mills, Portales, New Mexico
Recalled by: H.E. Butt Grocery Company, Corpus Christi, Texas (wholesaler), by telephone, February 26, 1982 with follow-up letters, March 1, 1982. Firm initiated recall
Distribution: Texas
Size & Quantity: 194 cases creamy and 325 cases chunky were distributed
Reason: Products were packed in a rodent and insect infested plant.

Product: Dona Maria brand Mole en Pasta (a condiment) in 245 gram glass jars labeled in Spanish, Recall #F-159-2
Code: Not coded
Manufacturer: Productos Dona Maria S.A., San Luis Potosi, S.L.P., Mexico
Recalled by: Groce-Wearden Company, Donna, Texas (wholesaler), by weekly bulletin and wholesale price list issued April 7, 14, 21, 28, 1982. Firm initiated recall
Distribution: South Texas
Size & Quantity: Firm estimates 336 jars remain on market
Reason: Product contains insect fragments.

Seizure Actions Filed:

Product: Aldea Brand Fresh Red Snaper (sic) (82-286-669)
Charge: Articles contain excessive levels of histamine, are decomposed and are misbranded in that the product is represented as being the fish "Red Snapper" when in fact the fish is not Red Snapper
Firm: Pan American Seafood, Inc., Fairfield, New Jersey
Filed: April 22, 1982 - U.S. District Court for the District of New Jersey at Newark; Civil #82-1255, FDC #63706.

####

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FDA Enforcement Report

Press Office
Food and Drug Administration

5600 Fishers Lane
Rockville, Md. 20857

301/443-4177

The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

PROSECUTION: A criminal action filed by FDA against a company or individual charging violation of the law. Prosecutions listed below have been filed with a court but not yet tried or concluded.

SEIZURE: An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods until the matter is resolved. The date listed is the date a seizure request is filed, not the date of seizure.

INJUNCTION: A civil action filed by FDA against an individual or company seeking, in most cases, to stop a company from continuing to manufacture or distribute products that are in violation of the law. Injunctions listed have been filed with the court but not concluded.

RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

May 19, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

NONE

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product:	Phentermine HCl, 30 mg. yellow hard gelatin capsules, in 100 and 1000 capsule bottles, an oral Rx anorexic (anti-obesity), Recall #D-083-2
Code:	Lot number 7-0781, EXP date 9/83
Manufacturer:	Camall Company, Detroit, Michigan
Recalled by:	Camall Company, Washington, Michigan, by telephone, April 30, 1982. Firm initiated recall

HE20. 4039:

Distribution: Michigan, New York, New Jersey, Pennsylvania, West Virginia, California

Size & Quantity: Firm estimates 13/1000 capsule bottles remain on market at wholesale level and are being returned to firm

Reason: Product failed content uniformity requirements.

Seizure Actions Filed:

Product: Cake Decorating Wafers (82-291-621 et al.)

Charge: Adulterated - Product bears or contains unsafe food color additives, namely FD&C Red #2 and Cochineal Red A

Firm: Walter Molzahn & Company, Chicago, Illinois

Filed: April 5, 1981 - U.S. District Court for the Northern District of Illinois; Civil #82 C-2114, FDC #63696.

Product: Pinto Beans (82-279-447/448)

Charge: Adulterated - Product was held under insanitary conditions

Firm: Northwest Produce Company, Inc., Yakima, Washington

Filed: April 30, 1982 - U.S. District Court for the Eastern District of Washington at Spokane; Civil #C82-335-RJM, FDC #63711.

Note: Seizure Action FDC #63664 which appeared on the Enforcement Report of March 24, 1982, should be corrected to read as follows:

Product: "Concentrated Orange Juice." The name "Beechnut" was inadvertently mentioned and should not have been since it is not the responsible firm.

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

May 26, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	(a) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes Black (0.25 ounce); (b) Dr. Olbrich's Combinal Dye for Eyebrows and Eyelashes - Brown (0.25 ounce); (c) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Blue (0.25 ounce), Recall #F-173/175-2
Code:	All codes
Manufacturer:	W. Pauli, Vienna, Austria
Recalled by:	Faces Enterprises, Ltd., Baltimore, Maryland (importer/distributor), by letter, April 23, 1982. Firm initiated recall. See FDA press release P82-16, April 9, 1982
Distribution:	Maryland, Virginia, Mississippi, California, Washington, D.C. and Georgia
Size & Quantity:	Firm estimates 100 tubes remain on market
Reason:	Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

HE 20. 4039:

Product: (a) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Black; (b) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Brown; (c) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Blue; (d) Dr. Olbrich's Combinal Dye for Hairs - Grey, in 0.25 ounce metal tubes, Recall #F-176/179-2
Code: All lots
Manufacturer: W. Pauli, Vienna, Austria
Recalled by: Arvo International Corporation, Salt Lake City, Utah (importer), by letter, week of April 19, 1982. Firm initiated recall. See FDA press release P82-16, April 9, 1982
Distribution: Nationwide
Size & Quantity: Firm has distributed 120 to 130 individual tubes in the past 18 months
Reason: Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

Product: (a) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Black; (b) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Brown; (c) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Blue in 0.25 ounce tubes, Recall #F-180/182-2
Code: All lots
Manufacturer: W. Pauli, Vienna, Austria
Recalled by: Anna M. Crispen, Inc., New York, New York (importer and distributor), by letter, on or about April 26, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 207 tubes were distributed. Firm estimates less than 50% remains on market
Reason: Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

Product: (a) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Black in 0.25 ounce tubes; (b) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Brown in 0.25 ounce tubes; (c) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Blue in 0.25 ounce tubes; (d) Dr. Olbrich's Combinal Dye for Hairs - Grey in 0.25 ounce tubes, Recall #F-183/186-2
Code: All lots
Manufacturer: W. Pauli, Vienna, Austria
Recalled by: C'est Francais International, Inc., Dallas, Texas (importer), by letter, on or about May 5, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates 578 tubes remain on market
Reason: Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: "Price's" Strawberry Ice Cream in half gallon cartons, Recall #F-170-2
Code: 606
Manufacturer: Price's Creamery, Inc., El Paso, Texas
Recalled by: Manufacturer, by letter, on or about March 24, 1982. Firm initiated recall complete
Distribution: El Paso,Texas and southern New Mexico
Size & Quantity: 316 cartons were recovered from market
Reason: Product contains undeclared nuts.

Product: Rhozyme P-11 Proteolytic Enzyme Product, used as an enzyme additive in meat tenderizers, baked goods and candy and sold in various size packages from several ounces to 150 pound drums, Recall #F-172-2
Code: 3-30678A, 3-30679B
Manufacturer: Rohm and Haas Delaware Valley Inc., Bristol, Pennsylvania
Recalled by: Corning Glass Works, Inc., Corning, New York, by telephone, February 22, 1982. Firm initiated recall complete
Distribution: Nationwide
Size & Quantity: Firm estimates none remains on market
Reason: Aflatoxin contamination.

Product: Vitatron Medical Pacemaker Analysers used to facilitate simple and rapid check-up of patients with pacemaker types C23, C2120 C2130, C2140 based on digital pulse analysis and threshold measurement, Recall #T-149-2
Code: Model MPA-1: serial numbers 02, 20, 24, 29, 30, 31, 33, 40, 65, 67, 72, 76, 92, 99, 136, 139, 251, 290, 1016, 1017, 1050, 1054; Model VA 1000: serial number 2018
Manufacturer: Vitatron Medical B.V., Dieren, The Netherlands (formerly represented by Vitatron Medical Inc., Newton, Massachusetts)
Recalled by: Manufacturer (represented by law firm Bingham, Dann & Gould, Boston, Massachusetts), by letter, March 30, 1982,and April 9, 1982. Firm initiated recall
Distribution: Florida, Louisiana, New Jersey, New York, Wisconsin, Pennsylvania, Texas, Massachusetts, Indiana, California
Size & Quantity: Approximately 40 analysers have been marketed in the United States since 1972
Reason: Incorrect use of the device's transmitter coil during threshold measurement may result in internal oscillation of the pacemaker's circuitry resulting in loss of capture.

Product: (a) Whole Blood (Human); (b) Red Blood Cells (Human); (c) Red Blood Cells (Human), Washed; (d) Single Donor Plasma (Human), Fresh Frozen; (e) Platelet Concentrate (Human); (f) Cryoprecipitated Antihemophilic Factor (Human); (g) Recovered Human Plasma, an extension of Recall #B-009/016-2 which appeared originally on the March 17, 1982 Enforcement Report

Code: (a) 1137T, 1249X, 1285X, 1820J, 1917T, 2241T, 2308S, 2433T, 2464R, 2477T, 2638T, 2733T, 2863R, 2874T, 3218J, 3221J, 3224J, 3225J, 3227J, 3230J, 3233J, 3236J, 3238J, 3245J, 3246J, 3247J, 3250J, 3554R, 3929P, 4073H, 4191R, 4270J, 4351S, 4626X, 4903X, 4916F, 4955X, 5057S, 5579X, 5599X, 5649X, 6822H, 6797X, 6825X, 7454Y, 9096X; (b) 156K, 227X, 404X, 693X, 1367K, 1617S, 1618X, 1624S, 1700X, 1701X, 1702X, 1838Y, 2677K, 2972R, 3005X, 3125T, 3203J, 3204J, 3205J, 3206J, 3208J, 3209J, 3212J, 3213J, 3214J, 3215J, 3216J, 3217J, 3219J, 3222J, 3223J, 3226J, 3228J, 3229J, 3231J, 3232J, 3234J, 3237J, 3239J, 3240J, 3241J, 3243J, 3244J, 3248J, 3249J, 3393X, 3492J, 3639T, 3741P, 3788S, 3818S, 3865S, 3865T, 3992S, 4013S, 4146J, 4271J, 4382P, 4384T, 4409H, 4537Y, 4610X, 4637X, 4704T, 4968S, 5040S, 5041S, 5042S, 5043S, 5044S, 5045S, 5047S, 5049S, 5051S, 5053S, 5054S, 5055S, 5056S, 5058S, 5059S, 5146Y, 5347V, 5442P, 5518Y, 5636K, 5656Y, 5829J, 6417S, 6471H, 6596X, 6683J, 6787X, 6789X, 6791X, 6792X, 6793X, 6794X, 6795X, 6796X, 6798X, 6799X, 6800X. 6801X, 6802X, 6803X, 6804X, 6805X, 6806X, 6807X, 6808X, 6809X, 6810X, 6811X, 6812X, 6813X, 6814X, 6815X, 6816X, 6817X, 6818X, 6820X, 6821X, 6822X, 6823X, 6824X, 6826X, 7381S, 7438S, 7686H, 8399J, 8451J, 8669X, 8754H, 9022J, 9025H, 9113F, 9286S, 9499P; (c) 3210J, 3235J, 3242J, 3444X, 4632H, 6783H, 6788X; (d) 156K, 227X, 1367K, 1617S, 1618S, 1624S, 1700X, 1701X, 2677K, 3005X, 3205J, 3206J, 3207J, 3208J, 3212J, 3213J, 3216J, 3492J, 3818S, 3992S, 4013S, 4014S, 4146J, 4409H, 4769S, 4968S, 5040S, 5041S, 5042S, 5043S, 5045S, 5047S, 5049S, 5051S, 5053S, 5054S, 5055S, 5056S, 5058S, 5059S, 5146Y, 5636K, 6787X, 6788X, 6789X, 6791X 6792X, 6793X, 6794X, 6795X, 6796X, 6798X, 6799X, 6800X, 6801X, 6802X, 6803X, 6804X, 6805X, 6806X, 6807X, 6808X, 6809X, 6810X, 6811X, 6812X, 6813X, 6814X, 6816X, 6817X, 6818X, 6820X, 6821X, 6822X, 6823X, 6824X, 6826X, 7438S, 8399J, 9022J, 9286S; (e) 156K, 543J, 1367K, 1617S, 1618S, 1624S, 1700X, 1701X, 2308S, 2677K, 3005X, 3203J, 3204J, 3206J, 3207J, 3209J, 3212J, 3214J, 3216J, 3217J, 3393X, 3492J, 3818S, 3992S, 4013S, 4146J, 4409H, 5040S, 5041S, 5042S, 5043S, 5044S, 5045S, 5047S, 5048S, 5049S, 5051S, 5053S, 5054S, 5055S, 5056S, 5058S, 5059S, 5347V, 5636K, 6787X, 6788X, 6789X, 6791X, 6792X, 6793X, 6794X, 6795X, 6796X, 6798X, 6799X, 6800X, 6801X, 6802X, 6803X, 6804X, 6805X, 6806X, 6807X, 6808X, 6809X, 6810X, 6811X, 6812X, 6813X, 6814X, 6816X, 6817X, 6818X, 6820X, 6821X, 6822X, 6823X, 6824X, 7381S, 7438S, 8399J, 8754H, 9286S; (f) 5442P; (g) 599K, 3243J

Manufacturer: Belle Bonfils Memorial Blood Center, Denver, Colorado

Recalled by: Manufacturer, by letter, May 5, 1982. Firm initiated recall

Distribution: Colorado
Size & Quantity: FDA estimates five percent remains on market
Reason: Products were distributed which: (1) were presumptively reactive for hepatitis B surface antigen (HBsAg); (2) could not be correlated to specific results within a series where presumptive reactives were noted; or (3) were collected from persons found to have previously tested HBsAg reactive.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Triacting Syrup, a decongestant antihistaminic drug, packed 12/4 fluid ounce bottles per case, Recall #D-084-2
Code: 0I382 EXP date 9/82, 0I383 EXP date 9/82
Manufacturer: L. Perrigo & Co., Allegan, Michigan
Recalled by: Manufacturer, by accepting returns from two own-label distributors between May 6, 1981 and March 8, 1982. Firm initiated recall complete
Distribution: Eastern, Midwest, and Central United States
Size & Quantity: Approximately 7,000 dozen bottles were distributed between October 14, 1980 and March 1981
Reason: Mold contamination.

Product: Rogenic Brand Sterile Injection, labeled "for use in adults only for the treatment of iron deficiency anemia," an Rx preparation in 10 ml. vials. It contains cyanocobalamin, iron, and liver injection, Recall #D-085-2
Code: 81H046
Manufacturer: Carter-Glogau Laboratories, Inc., Glendale, Arizona
Recalled by: O'Neal, Jones & Feldman, Inc., Maryland Heights, Missouri (distributor), by letter, May 10, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 5,754 vials were distributed between December 7, 1981 and April 28, 1982
Reason: Mislabeled - The labeling indicates the product contains 500 milligrams of cyanocobalamin whereas the correct labeling is 500 micrograms.

Product: Clindex Capsules, an oral Rx combination drug with cardiorenal action, packaged in 100, 500 and 1000 capsule size bottles, Recall #D-086-2
Code: Control number 110018, EXP 11/83
Manufacturer: Chelsea Laboratories, Inc., Inwood, New York
Recalled by: Manufacturer, by memorandum, April 19, 1982. Firm initiated recall complete

Distribution: One consignee in New York
Size & Quantity: 3187 units were distributed. FDA estimates less than 10 percent remains on market
Reason: Product failed content uniformity for clidinum bromide.

Product: (a) Maya Brand Shell on Shrimp, 10/5 pound boxes, Nica Brand Shell on Shrimp, 50 pound boxes, Tivoli Brand Shell on Shrimp, 8/5 and 10/5 pound boxes; (b) Celebrity Brand IQF Shrimp, 6/6 pound and 40 pound boxes, Maya Brand IQF Shrimp, 40 pound boxes, NICA Brand IQF Shrimp, 40 pound boxes; (c) Maya Brand Tail on Shrimp, 10/5 pound boxes; (d) Celebrity Brand Lobster Tails, 4/10 pound boxes, Nica Brand Lobster Tails, 2/10 pound ties, Maya Brand Lobster Tails, 2/10 pound ties; (e) Nica Brand Ocean Pike, 50 pound boxes; (f) Nica Brand Sea Trout, 50 pound boxes; (g) Nica Brand Fish Fillets, 50 pound boxes, Recall #F-163/169-2
Code: All lots and sizes which arrived on the vessel Atlantic Freeze Voyager #40
Manufacturer: Empresa Nicaraguense de Productos, Managua, Nicaragua
Recalled by: World Commerce Corporation, Miami, Florida (importer), by letter, April 9, 1982. Firm initiated recall
Distribution: Midwest and Eastern United States
Size & Quantity: 259,745 pounds were distributed. FDA estimates 40 percent remains on market
Reason: Thawing and decomposition of the products due to temperature abuse during the voyage or unloading.

Product: R&H Brand Ready to Use Coffee Syrup Ice Cream Topping, 96 fluid ounces, Recall #F-171-2
Code: 285/01J
Manufacturer: Richardson & Holland Inc., Seattle, Washington
Recalled by: Manufacturer, by telephone, December 10, 1981. Firm initiated recall complete
Distribution: Maryland, Florida, Texas, Minnesota, Utah, Washington, Alaska, Oregon
Size & Quantity: 62 cases of 6/96 fluid ounce cans were distributed
Reason: Yeast contamination.

Product: (a) ALT (GPT) Spin Chem Test Reagent, used to test the ALT (Alanine Aminotransferase) levels in the blood; (b) AST (GOT) Spin Chem Test Reagent, used to test SGOT (ALT) (Aspartate Aminotransferase) levels in the blood, Recall #T-147/148-2
Code: (a) (1) Product #89077, 20 ml., lot #746011; (2) product #89079, 6.5 ml., lot #746021, #746031, #746042; (3) product #50080, 6.5 ml., lot #746041 (private), (b) (1)

product #89047, 20 ml., lot #749111; (2) product #89049, 6.5 ml., 749121, #749142; (3) product #50079, 6.5 ml., lot #749141 (private), #749190 (private)

Manufacturer: Smith Kline Instruments, Inc., Sunnyvale, Calfiornia

Recalled by: Manufacturer, by letter, March 16, 1982 and subrecalled by Roche Analytical Instruments, Inc., Nutley, New Jersey, Firm initiated recall

Distribution: Nationwide

Size & Quantity: (a) Approximately 10,000 boxes; (b) approximately 8,500 boxes were distributed

Reason: These specific lots contain an insufficient amount of lactate dehydrogenase, which depending on the amount of pyruvate in the sample will affect the lag time to a greater or lesser degree.

Product: Clostridium Botulinum Type D Horse Serum Antitoxin for Mouse Neutralization Test - Injectable, Recall #T-151-2

Code: 76-0342

Manufacturer: Centers for Disease Control, Atlanta, Georgia

Recalled by: Manufacturer, by letter, January 25, 1982. Firm initiated recall complete

Distribution: Nationwide, Israel, Switzerland

Size & Quantity: Eight vials were shipped

Reason: Product was shipped after the expiration date.

Seizure Actions Filed:

Product: Mole, a seasoning paste (82-314-683)

Charge: Adulterated - Product contains insect fragments; Misbranded - Labeling not in English language

Firm: Dona Maria, S.A. Mexico

Filed: April 16, 1982 - U.S. District Court for the District of Illinois, Eastern Division at Chicago; Civil #82C-229, FDC #63699.

Product: Sunflower Seeds (82-236-097)

Charge: Product consists in part of a filthy substance by reason of the presence therein of insect larvae and insect damaged seed; product was held under insanitary conditions whereby it became contaminated with filth

Firm: David & Sons, Division of Sunmark Companies, Inc., St. Louis, Missouri

Filed: April 19, 1982 - U.S. District Court for the Eastern District of Missouri, Eastern Division at St. Louis; Civil #82-0589-C(C), FDC #63692.

Product: Sorghum Syrup, Cane Molasses, Sugar Syrup (82-235-833)
Charge: Adulterated - A substance, namely corn syrup was substituted in part for sorghum syrup, cane molasses and cane syrup; Misbranded - False and misleading labeling; violation of standards
Firm: Norris Brothers, West Monroe, Louisiana
Filed: May 7, 1982 - U.S. District Court for the Southern District of Mississippi, Jackson Division; Civil #J82-0245(C), FDC #63710.

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June 2, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	All canned salmon in 7.75 ounce size metal cans produced by the Naknek, Alaska, plant in 1980 and 1981. The recall includes all species processed under all brand labels, Recall #F-187-2
Code:	All codes produced in 1980 and 1981. The cans have a two-line code stamped on the top lid: P followed by a four digit number over a bottom line of four or five characters or symbols beginning with R, P or C
Manufacturer:	Red Salmon Company, Naknek, Alaska
Recalled by:	Manufacturer, by letter, May 19, 1982. Firm initiated recall. See FDA press releases P82-4, February 18, 1982; P82-10, March 19, 1982; P82-14, March 31, 1982; P82-15, April 8, 1982; P82-18, May 20, 1982 and FDA talk paper T82-15, March 5, 1982
Distribution:	Nationwide and international
Size & Quantity:	Firm distributed 93,193 cases (24 cans/case) nationwide and 92,194 cases (24 cans/case) internationally
Reason:	Some of the cans may be defective which could affect the integrity of the product.

HE 20. 4039:

Product: (a) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Black; (b) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Brown; (c) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Blue, in 0.25 ounce metal tubes, Recall #F-188/190-2
Code: All lots
Manufacturer: W. Pauli, Vienna, Austria
Recalled by: Correlations, Inc., Dallas, Texas (distributor), by letter, April 23, 1982. Firm initiated recall. See FDA press release P82-16, April 9, 1982
Distribution: North Carolina, Texas, Indiana, Michigan, Arkansas, Nevada, New Mexico, Maryland
Size & Quantity: Firm estimates 190 tubes remain on market
Reason: Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

Product: (a) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Brown; (b) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Black; (c) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Blue; (d) Dr. Olbrich's Combinal Dye for Hairs - Gray in 0.25 ounce metal tubes, Recall #F-191/194-2
Code: All lots
Manufacturer: W. Pauli & Company, Vienna, Austria
Recalled by: Tru-Discount, El Segundo, California (distributor), by letter, on or about April 19, 1982. Firm initiated recall. See FDA press release P82-16, April 9, 1982
Distribution: Southern California
Size & Quantity: Firm estimates 200 tubes remain on market
Reason: Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: "Raphadex B" Screening Test, Antibody to Hepatitis B Surface Antigen (anti-HBs) (Chimpanzee) Coated Human Red Blood Cells (Lyophilized), packaged in 110 test and 440 test kits. Product is a reversed passive hemagglutination screening test of third generation sensitivity for the detection and confirmation of Hepatitis B surface antigen in human serum, Recall #B-020-2
Code: Kits and vials coded "RBST203 EXP 22AUG82"
Manufacturer: Ortho Diagnostic Systems, Inc., Raritan, New Jersey

Recalled by: Manufacturer, by letter, April 23, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: 3254/110 test kits and 314/440 test kits were distributed
Reason: The reagent cells in the kit are no longer exhibiting third generation sensitivity for the detection of hepatitis B surface antigen. This reduced sensitivity could result in weak positive or false negative test results.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Reagent Red Blood Cells, Cell Panels, Recall #B-019-2
Code: 2-4% v/v lot #LL2-C1 and 4-6% v/v lot #LH2-C1, EXP date 3/22/82
Manufacturer: Accugenics, Inc., Costa Mesa, California
Recalled by: Manufacturer, by letter, March 10, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: Firm estimates none remains on market
Reason: The antigen chart for both products identify Cell Number Seven as N-Positive; however, it was actually N-Negative.

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FDA Enforcement Report

Press Office
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The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

PROSECUTION: A criminal action filed by FDA against a company or individual charging violation of the law. Prosecutions listed below have been filed with a court but not yet tried or concluded.

SEIZURE: An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods until the matter is resolved. The date listed is the date a seizure request is filed, not the date of seizure.

INJUNCTION: A civil action filed by FDA against an individual or company seeking, in most cases, to stop a company from continuing to manufacture or distribute products that are in violation of the law. Injunctions listed have been filed with the court but not concluded.

RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

June 9, 1982

Recalls and Field Corrections:

Class I · *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II · *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Klotrix Slow Release Tablets, 10 meq/tablet equivalent to 750 mg. potassium chloride, an orange film-coated controlled release Rx drug for potassium therapy, Recall #D-087-2
Code:	Lot MGM88 - use by 7/83 in unit dose packages, MJM13 - use by 9/84 in 100 tablet bottles, MJM14 - use by 9/84 in 100 tablet bottles and use by 9/83 was distributed in 4 tablet bottles as physician samples, MJM16 - use by 9/84 in 100 tablet bottles
Manufacturer:	Mead Johnson & Company, Evansville, Indiana
Recalled by:	Manufacturer, by mailgram, May 14, 1982. Firm initiated recall
Distribution:	Nationwide and Puerto Rico
Size & Quantity:	Firm estimates 6,500,000 doses remain on market
Reason:	Product does not meet dissolution specifications.

HE 20.4039:

Product: "Extrin's Trinex 713" Artificial Butter Flavor, one gallon plastic jugs used as flavoring in baked goods, Recall #F-195-2
Code: Lot #R-74094
Manufacturer: Crompton & Knowles Corporation, Fair Lawn, New Jersey
Recalled by: Manufacturer, by telephone, January 26, 1982 with follow-up letter, April 15, 1982. Firm initiated recall complete
Distribution: New York
Size & Quantity: 30/1 gallon jugs were distributed
Reason: Product mix-up. Product labeled as Trinex 713, Artificial Flavor actually contains Triton-X-100, a non-ionic detergent.

Product: Freeze Dried Pink Peppercorn, an exotic imported spice in unlabeled plastic bags, Recall #F-197-2
Code: None
Manufacturer: Unknown
Recalled by: Swiss Chalet Fine Foods, Inc., Miami, Florida, by letter May 7, 1982. Firm initiated recall.
Distribution: Nationwide
Size & Quantity: 21 one-pound containers were distributed
Reason: Product contain *Schinus terebinthifolius* which is not an approved food additive in the United States nor is it generally recognized as safe (GRAS).

Product: Canned Tuna packed in 3-1/4, 3-1/2, 6, 6-1/2, 7, 12-1/2 and 13 ounce cans, Recall #F-204-2
Code: Products packed in Honolulu in 1981 and 1982 under the following labels: Bumble Bee, Mid Pacific, Coral, and Cloverleaf. Stamped on lids are the numbers 21 or 22 on the top line followed by two or three other numbers
Manufacturer: Bumble Bee Seafoods, Division of Castle & Cooke, Inc., Honolulu, Hawaii
Recalled by: Manufacturer, by letter, June 7, 1982. Firm initiated recall. See FDA press release P82-24, June 4, 1982
Distribution: Nationwide
Size & Quantity: Firm estimates about 40 million cans were packed at the Honolulu plant in 1981 and 1982, and distributed 24 and 48 cans to a case
Reason: Some cans have been found to have a small hole.

Product: (a) Red Blood Cells (Human); (b) Platelet Concentrate (Human): (1) intended for transfusion and (2) outdated for further manufacturing use; (c) Cryoprecipitated Antihemophilic Factor (Human); (d) Recovered Human Plasma, an extension of Recall #B-009/016-2 which appeared originally on the March 17, 1982 Enforcement Report

Code: (a) 3207J; (b) [1] 6826X, [2] 227X, 9022J, 6343S; (c) 4637X; (d) 404X, 693X, 1838Y, 2267R, 2878T, 2972R, 3125T, 3243J, 3258T, 3444X, 3554R, 3741P, 3788S, 4382P, 4537Y, 4869X, 4887X, 4931X, 4940X, 4941X, 5518Y, 5656Y, 5829J, 6417S, 6683J, 7381S, 8451J, 9113P, 9499P
Manufacturer: Belle Bonfils Memorial Blood Center, Denver, Colorado
Recalled by: Manufacturer, by letter, May 13 and 19, 1982. Firm initiated recall
Distribution: Colorado, California, Florida, Texas, Illinois, New York, Italy
Size & Quantity: Undetermined
Reason: Products were distributed which: (1) were presumptively reactive for hepatitis B surface antigen (HBsAg); (2) could not be correlated to specific results within a series where presumptive reactives were noted; or (3) were collected from persons found to have previously tested HBsAg reactive.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Wilderness Foods Apple Juice, 46 ounce cans, Recall #F-196-2
Code: S106A/11140, S106C/11130, S106D/11130, S106C/11170
Manufacturer: Wilderness Foods Division, Cherry Central Co-Op, Sodus, Michigan
Recalled by: Cherry Central Co-Op Inc., Traverse City, Michigan, by visit, April 22, 1982. Firm initiated recall
Distribution: Minnesota, Wisconsin, Iowa, Michigan
Size & Quantity: 6,400 cases (12/46 fluid ounce cans) were distributed
Reason: Minnesota Department of Agriculture found evidence of corrosion at the can code. The cans were fractured at the code mark during coding. Leakage occurred due to the cut lids.

Product: Sexton Boiled Onions, 5 pound 10 ounce cans, product of Belgium, (a) Tiny Boiled Onions, 425-475 Count; (b) Small Boiled Onions, 235-275 Count, Recall #F-198/199-2
Code: (a) Reorder #32755, Tiny Boiled Onions, 425-475 count; (b) reorder #32763, Small Boiled Onions, 235-275 count
Manufacturer: La Corbeille, Antwerp, Belgium
Recalled by: John Sexton & Company, Chicago, Illinois, by telephone, April 5, 1982. Firm initiated recall
Distribution: All states east of the Rocky Mountains
Size & Quantity: (a) 3,024/6 cans per case; (b) 938/6 cans per case were distributed
Reason: The cans have pinhole leaks.

Product: Calf milk replacer feeds in 50 pound bags labeled as containing oxytetracycline - (a) Hi-Per High Performance Veal Pre-Starter Feed, oxytetracycline 800 g/ton, neomycin sulphate 1600 g/ton; (b) Hi-Per High Performance Veal Starter Feed - 63 g/ton oxytetracycline; (c) Hi-Per High Performance Veal Finisher Feed - 63 g/ton oxytetracycline, Recall #V-016/018-2

Code: Products were manufactured between June 1981 and December 7, 1981. Lot numbers (a) 286, 224, 175, 306, 253; (b) 310, 224, 225, 286, 306, 285, 254, 307; (c) 308, 273, 226, 257, 274, 285, 309, 311, 225, 275, 176, 177, 286, 334, 335, 323, 307, 283, 336, 328, 329, 324, 322

Manufacturer: Ridge Road Farms, Elroy, Wisconsin

Recalled by: Midor Ltd., Elroy, Wisconsin, by letter, March 9, 1982. Firm initiated recall complete

Distribution: North Carolina, Virginia, New Jersey, Pennsylvania, New York

Size & Quantity: (a) 410/50 pound bags; (b) 1426/50 pound bags; (c) 5042/50 pound bags were shipped

Reason: Products were formulated using a premix which was not medicated. The finished calf milk replacer feeds are labeled as medicated when, in fact, they contain no medication. The problem was discovered by a Wisconsin Department of Agriculture inspection.

Injunction Action Filed:

Against: Ovutron Corporation, and Russell F. Bullock and June E. Bullock, individuals, Las Vegas, Nevada

Product: Ovutron Device (claimed to be effective for contraception and conception by allegedly detecting the time of a woman's ovulation) (82-247-906)

Charge: Adulterated - Products are Class III devices that are required to have in effect an approved application for premarket approval, and there is no such application; Misbranded - Labeling represents and suggests, inter alia, that they are effective for use in contraception, conception, family planning, and determining the time of onset of ovulation, and that tests and studies have been conducted which prove the effectiveness of the "Ovutron," which suggestions and representations are false and misleading since they are contrary to fact; their labeling fails to bear adequate directions for use; they were manufactured in an establishment not duly registered under 21 U.S.C. Section 360, and no notice respecting their introduction or delivery for introduction into interstate commerce was provided to the FDA as is required by law; and the defendants did not submit to FDA a list of the device, as is required by law

Filed: March 9, 1982 - U.S. District Court for the District of Nevada at Las Vegas; Civil #LV-82-140 HEC, INJ #996.

Seizure Actions Filed:

Product:	Canthaxanthin & Carotene (tanning tablets) (82-311-496)
Charge:	Product is not a hair dye and it contains color additives, which are unsafe within the meaning of the law because there is no regulation in effect
Firm:	Cosmetest Corporation, East Rutherford, New Jersey
Filed:	May 4, 1982 - U.S. District Court for the District of New Jersey at Newark; Civil #82-1396, FDC #63704.

Product:	Elbow Macaroni Products (82-275-028)
Charge:	Adulterated - Product contains insects
Firm:	Freiria & Company, Inc., Puerto Nuevo, Puerto Rico
Filed:	May 10, 1982 - U.S. District Court for the District of Puerto Rico; Civil #82-1149, FDC #63714.

Product:	Bandages (82-252-626 et. al.)
Charge:	Adulterated - Products have been prepared, packed and held under insanitary conditions whereby they may have been contaminated with filth; and they are devices and the methods used in, and the facilities and controls used for their manufacture, packing and storage are not in conformity with applicable requirements because the manufacture does not conform to good manufacturing practices as prescribed in the regulation to assure that such devices meet the requirements of the Federal Food, Drug, and Cosmetic Act as to safety and efficacy and are otherwise in compliance with the Act
Firm:	Medex Products Corporation, Buffalo, New York
Filed:	June 1, 1982 - U.S. District Court for the Western District of New York at Buffalo; Civil #CIV 82-474, FDC #63723.

Product:	Food Products (82-252-340 et. al.)
Charge:	Adulterated - Products were held under insanitary conditions whereby they may have become contaminated with filth and certain of the articles consist in part of filthy substances by reason of the presence of rodent excreta pellets
Firm:	R. Pusatere, Inc., Troy, New York
Filed:	June 2, 1982 - U.S. District Court for the Northern District of New York at Albany; Civil #CI 82-0378, FDC #63722.

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FDA Enforcement Report

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June 16, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	(a) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Black; (b) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Brown; (c) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Blue; (d) Dr. Olbrich's Combinal Dye for Hairs - Grey, in 0.25 ounce metal tubes, Recall #F-200/203-2
Code:	All lots
Manufacturer:	W. Pauli & Company, Vienna, Austria
Recalled by:	Christine Valmy of Palos Verdes (doing business as Konin Japierre, Inc.), Torrance, California (distributor), by letter, April 26, 1982. Firm initiated recall. See FDA press release P82-16, April 9, 1982
Distribution:	California
Size & Quantity:	Firm estimates 50 tubes remain on market
Reason:	Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

HE 20. 4039:

Product: Prepodyne Solution, a non-irritating "Tamed Iodine" (poloxamer-iodine complex) topical skin antiseptic in 1 gallon, 1 pint and 6 ounce bottles, and 50 gallon drums, Recall #D-088-2
Code: Lot #C109-756, EXP 9/84; C203-197, EXP 3/85; C203-137, EXP 3/85
Manufacturer: West Agro-Chemical, Inc., Chicago, Illinois
Recalled by: West Chemical Products Inc., Princeton, New Jersey, by telex, May 7, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: 550 cases of 6-1 gallon bottles under the Amsco label and 35 cases of 6-1 gallon bottles under the West label; 1904 cases of 12-1 pint bottles, 288 cases of 24-6 ounce bottles and 18-50 gallon drums were distributed
Reason: Some of the product has been found to be contaminated with Pseudomonas aeruginosa bacteria, which may cause infections.

Product: Geisha Brand Albacore Solid White Tuna in Water, in 3-1/2 ounce and 7 ounce cans, an extension of Recall #F-160-2 which appeared on the May 12, 1982 Enforcement Report
Code: 3-1/2 ounce cans: H20B7/841N1; 7 ounce cans: H20B2/841N1, H21A2/841N1, H21A3/841N1, H21B2/841N1, H21B3/841N1, H24B2/841N1, H24B3/841N1, H24B6/841N1
Manufacturer: Neptune Packing Corporation, Mayaguez, Puerto Rico (packer)
Recalled by: Nozaki America, Inc., New York, New York (distributor), by visit, May 17, 1982, and letter, May 19, 1982. Firm initiated recall
Distribution: New England area
Size & Quantity: Firm estimates 494 cases of the 3-1/2 ounce cans and 2,453 cases of the 7 ounce cans remain on market
Reason: Odor and taste of lubricating (machine) oil in the product.

Product: Geisha Brand Albacore Chunk White Tuna in Water in 6-1/2 ounce cans, Recall #F-206-2
Code: H21A1/741N1
Manufacturer: Neptune Packing Corporation, Mayaguez, Puerto Rico (packer)
Recalled by: Nozaki America, Inc., New York, New York, by letter, May 26, 1982. Firm initiated recall
Distribution: New England area
Size & Quantity: Firm estimates 5 cases remain on market
Reason: Odor and taste of lubricating (machine) oil in the product.

Product: Mahi-Mahi Frozen Fish Fillets, 50 pound cartons, Recall #F-210-2
Code: Lot #'s 47322, 47321, 47370, 47412, 47413
Manufacturer: Unknown. Pan American Seafood, Fairfield, New Jersey is the importer
Recalled by: Pan American Seafood, Glendale, California, by telephone and letter, April 12, 1982. Firm initiated recall

Distribution: Western United States
Size & Quantity: 170/50 pound cases were distributed
Reason: High histamine levels.

Product: Robertshaw Demand Valve, designed to provide oxygen to a breathing or non-breathing patient and to be used by emergency fire/rescue personnel, physicians and dentists, Recall #T-153-2
Code: Part 900-002-063, Serial #'s 2010609 thru 2010679
Manufacturer: Robertshaw Controls Company, Anaheim, California
Recalled by: Manufacturer, by telephone, March 8-9, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 71 units were distributed
Reason: The stainless steel seat within the demand valve body may become dislodged.

Product: Source Plasma (Human), an extension of Recall #B-018-2 which appeared on the April 14, 1982 Enforcement Report
Code: Unit #546079
Manufacturer: Plasma Services of San Antonio I, San Antonio, Texas
Recalled by: Plasma Services, Division of Blood Systems, Inc., Scottsdale, Arizona, by telex, February 18, 1982. Firm initiated recall
Distribution: Vienna, Austria
Size & Quantity: One unit involved
Reason: The unit of Source Plasma (Human) tested reactive for hepatitis B surface antigen but was labeled as non-reactive and distributed.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Triple Antibiotic Ointment (bacitracin 400 units, neomycin sulfate 5 mg./and polymyxin B sulfate 5000 units per gram), an OTC antibiotic/anti-infective/healing aid, topical ointment in 1/2 and 1 ounce tubes, Recall #D-089-2
Code: Lot #7505
Manufacturer: Ambix Laboratories, Division of Organics Corporation of America, E. Rutherford, New Jersey
Recalled by: Manufacturer, by letter, May 13, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 23,665 one ounce tubes and 21,312 one half ounce tubes were distributed
Reason: Product is subpotent in bacitracin and polymyxin B sulfate ingredients.

Product: Phenylbutazone Alka Capsules, an oral Rx drug for the treatment of rheumatism, packaged in 100 capsule boxes in unit dose strips and in plastic vials containing 30, 50 and 100 capsules, Recall #D-090-2
Code: All lots
Manufacturer: Danbury Pharmacal, Danbury, Connecticut
Recalled by: Kaiser Foundation Hospitals, Pharmacy Division, Berkeley, California, by letter, February 2, 1982. Firm initiated recall complete
Distribution: California
Size & Quantity: 54,000 capsules were distributed
Reason: Marketed without an approved New Drug Application.

Product: Orange, Cherry and Lime Flavor Popsicles, 2-1/2 fluid ounces, packed 24/box for unit sales, Recall #F-207/209-2
Code: None
Manufacturer: Beatrice Foods Company, doing business as Meadow Gold Ice Cream, Nashville, Tennessee
Recalled by: Manufacturer, by route driver pick-up, April 16, 1982. Firm initiated recall complete
Distribution: Middle Tennessee and southern Kentucky
Size & Quantity: Firm estimates none remains on market
Reason: Pinhole leaks in the stainless steel popsicle molds in the freezing machine could permit the calcium chloride-water brine to contaminate the popsicles and cause an off taste.

Product: Calbiochem-Behring Tri-Partigen IgC Bulk Pack for In-vitro diagnostic use, Recall #T-116-2
Code: Lot #695006 Exp. date March 83 (Bulk pack) Catalog #695010
Manufacturer: Calbiochem-Behring Corporation, La Jolla, California
Recalled by: Manufacturer, by telephone, January 12-14, 1982, and follow-up letter on or about January 15, 1982. Firm initiated recall
Distribution: Arizona, Colorado, Idaho, Illinois, Kentucky, Massachusetts, Michigan, Minneapolis, North Dakota, Oregon, Texas, Utah and Washington State
Size & Quantity: 40 bulk packs were distributed
Reason: Product contained Tri-Partigen IgA Radial Immunodiffusion Plates instead of the Tri-Partigen IgG Radial Immunodiffusion Plates.

Product: Ames TDA Quinidine Test Kits, an In-vitro diagnostic used as an aid in monitoring Quinidine therapy. The test kit is a fluorescent immunoassay for quinidine in serum or plasma, Recall #T-154-2
Code: 3798 200, lot #9003012, EXP 1/83

Manufacturer: Ames Division, Miles Laboratories, Inc., South Bend, Indiana
Recalled by: Ames Division, Miles Laboratories, Inc., Elkhart, Indiana, by letter, April 21, 1982. Firm initiated recall
Distribution: Nationwide, Australia, Belgium, France, United Kingdom, The Netherlands, Spain, West Germany
Size & Quantity: 457 kits were manufactured
Reason: The unexpected rapid degradation of the Fluorogenic Drug Reagent (FDR) causes the calibration curve to flatten at the lower end. This diminishes the ability to quantify quinidine concentrations below 2.5 mg/ml.

Product: Stokely Van Camp's Finest French Style Sliced Green Beans, 16 ounce cans, 24 cans per case, Recall #F-205-2
Code: Cans- "DBK7/G248B"; cases- "DG248B"
Manufacturer: Kuner-Empson Company, Division of Stokely-Van Camp, Inc., Brighton, Colorado
Recalled by: Stokely-Van Camp, Inc., Indianapolis, Indiana, by destruction statement, October 8, 1981. Firm initiated recall complete
Distribution: California, Washington State, Hawaii
Size & Quantity: Firm estimates none remains on market
Reason: Swollen cans.

Product: Q-Pak Chemistry Control Serum II (Unassayed); a control serum containing constituents generally in the abnormal range, used to assess the precision of laboratory procedures; 25 ml. vial, 10 vials per carton, Recall #T-161-2
Code: List #045-711, lot #3465B003B; EXP. 6/84
Manufacturer: Hyland Diagnostics, Division of Travenol Laboratories, Inc., Round Lake, Illinois
Recalled by: Hyland Diagnostics, Division of Travenol Laboratories, Inc., Deerfield, Illinois, by visit, May 17, 1982. Firm initiated recall complete
Distribution: New York, Arizona, Pennsylvania, Louisiana, Mississippi
Size & Quantity: Firm estimated 2,900 vials were on market at time of recall
Reason: A capping problem resulted in the instability of some of the constituents in some of the vials.

Seizure Actions Filed:

Product: Rice (82-274-795)
Charge: Adulterated - Product contains insects and has been rodent gnawed
Firm: Farmers Rice Company of Puerto Rico, Inc., Guaynabo, Puerto Rico
Filed: May 24, 1982 - U.S. District Court for the District of Puerto Rico at San Juan; Civil #82-1080, FDC #63719.

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FDA Enforcement Report

Press Office
Food and Drug Administration
5600 Fishers Lane
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The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

June 23, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	"Mister Max" brand imported bleached rawhide chew bones and chips, packaged in individual heat-sealed plastic pouches. There are two types: 2-inch by 2-inch rawhide chips (3-1/2 ounce size) and 4 sizes of chews in the shape of a bone (4, 6, 9 and 12 inches), Recall #V-019-2
Code:	There are no codes or lot numbers
Manufacturer:	Ssang Young Corporation, Seoul, South Korea
Recalled by:	Award Service, Inc., Mountain View, California (distributor), by visit, approximately September 1981. Firm initiated recall complete
Distribution:	California, Nevada
Size & Quantity:	5,126 cases at 12/case were shipped
Reason:	The rawhide chews have been linked to adverse reactions in a number of cases.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

HE 20. 4039:

Product: Neptuna Brand Chunk White Tuna in Water in 6-1/2 ounce cans, Recall #F-211-2
Code: H21A1 over 741N1 embossed on one of the can lids
Manufacturer: Neptune Packing Corporation, Mayaguez, Puerto Rico
Recalled by: King Neptune Sales Corporation, New York, New York, by letter, May 26, 1982. Firm initiated recall
Distribution: Maryland
Size & Quantity: 105 cases (48 cans/case) were packed
Reason: Machine oil smell in product.

Product: Gently Bare Wax Hair Removal System; product consists of the following: 3-1/2 ounce heating dish with (soft) wax, a roll of fabric stripping for wax removal, instructions, wax applicator, and is used for the removal of unwanted hair from the body, Recall #F-212-2
Code: All manufactured lots are involved and include lot numbers 0211, 0212, 0213, 0214
Manufacturer: Andrea Raab Corporation, Brooklyn, New York
Recalled by: Manufacturer, by telephone and letter, May 21, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 75,804 units were shipped
Reason: After applying according to directions, product was difficult to remove.

Product: Sage Syringe Infusion Pumps used for infusion of anticoagulants and for general clinical use, Recall #T-162-2
Code: Model numbers 240A and 242A, all serial numbers
Manufacturer: Orion Research Inc., Cambridge, Massachusetts
Recalled by: Manufacturer, by telephone, April 23, 1982. Firm initiated recall
Distribution: Nationwde and international
Size & Quantity: 1,777 pumps were distributed
Reason: Possibility of primer switch sticking causing increased infusion rate if the device is disinfected with certain chemical solutions.

Product: Pneu-Dart, an animal immobilization dart containing succinylcholine chloride dihydrate in dosages of 1 to 32 mg., Recall #V-020-2
Code: All lots
Manufacturer: Pneu-Dart, Inc., Williamsport, Pennsylvania
Recalled by: Manufacturer, by letter, March 10, 1982. Firm initiated recall
Distribution: Prior to 1979, nationwide; since that time, Pennsylvania
Size & Quantity: Firm estimates 1500 remain on market
Reason: The investigational new animal drug exemption was withdrawn.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

NONE

Seizure Actions Filed:

Product: Miscellaneous Stored Foods (82-279-630)
Charge: Adulterated - Products consist in part of a filthy substance (rodent and insect filth)
Firm: Mekong Market, Seattle, Washington
Filed: May 11, 1982 - U.S. District Court for the Western District of Washington at Seattle; Civil #C82-553, FDC #63713.

Product: Various Foodstuffs (82-243-030/038)
Charge: Adulterated - Products have been held under insanitary conditions and contain rodent excreta pellets, rodent urine, and insects
Firm: Bombay Bazar Wholesale Distributors, Berkeley, California
Filed: May 28, 1982 - U.S. District Court for the Northern District of California at San Francisco; Civil #C-82-2705 RHS, FDC #63726.

Product: Cranberry Apple Drink (82-281-449)
Charge: Adulterated - Vitamin C omitted; Misbranded - Label states that product contains Vitamin C when it does not
Firm: Derry Products Company, Middletown, New York
Filed: June 4, 1982 - U.S. District Court for the Eastern District of Louisiana at New Orleans; Civil #82-2357, FDC #63687.

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FDA Enforcement Report

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

June 30, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product: (a) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Black; (b) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Brown; (c) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Blue; (d) Dr. Olbrich's Combinal Dye for Hair - Gray, in 0.25 ounce tubes, Recall #F-214/217-2
Code: All lots
Manufacturer: W. Pauli, Vienna, Austria
Recalled by: Nestore Distributing Company, Danville, California (distributor), by telephone, April 15, 1982. Firm initiated recall. See FDA press release P82-16, April 9, 1982
Distribution: California, Colorado, Alaska
Size & Quantity: Approximately 600 tubes were distributed
Reason: Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

Product: (a) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Black; (b) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Brown; (c) Dr. Olbrich's Combinal Dye for the Eyebrows and Eyelashes - Blue; (d) Dr. Olbrich's Combinal Dye for Hair - Gray, in 0.25 ounce metal tubes, Recall #F-218/221-2

HE20.4039:

Code: All lots
Manufacturer: W. Pauli, Vienna, Austria
Recalled by: Let's Face It, Santa Rosa, California (distributor), by letter, May 3, 1982. Firm initiated recall. See FDA press release P82-16, April 9, 1982
Distribution: Northern California, Colorado
Size & Quantity: Firm estimates 430 tubes of all colors were distributed
Reason: Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

Product: Infant Ventilator, Model 105, used in providing respiratory support to infant, pediatric, or adult patients who exhibit various degrees of respiratory distress, Recall #T-152-2
Code: Model 105
Manufacturer: Healthdyne, Inc., Marietta, Georgia
Recalled by: Manufacturer, by telephone beginning August 25, 1981. Firm initiated recall
Distribution: Nationwide, Canada, Japan
Size & Quantity: Only 2 of the 110 units distributed need to be returned and retrofitted
Reason: Units did not have check valves on the oxygen and air inlets causing the backflow of oxygen gas from the ventilator into other hospital gas supplies.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Kal's Kids Children's Chewable Vitamins and Minerals in 180 and 60 tablet bottles, Recall #F-213-2
Code: Lot #6329
Manufacturer: American Nutritional Laboratories, Anaheim, California
Recalled by: Makers of Kal, Inc., Canoga Park, California, by letter, March 23, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates 30,000 tablets remain on market
Reason: Product contains niacin and not niacinamide as labeled.

Product: Hemochron Blood Coagulation Test Tubes, CGA, Diatomaceous Earth and Glass Activated - Evacuated, for In-vitro determination of activated whole blood coagulation time. Each test tube contains diatomaceous earth, 20 mg. and glass particulate - 100 mg., a unit box is 100 test tubes, Recall #T-155-2

Code: Control #'s 6484475, 6494475, 6494476, 6414476, EXP dates between August 3 and October 20, 1982. Only the CGA types of test tubes are involved
Manufacturer: International Technidyne Corporation, Edison, New Jersey
Recalled by: Manufacturer, by telephone followed by letters mailed May 4-6, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: FDA estimates 2,000 boxes of 100 tubes remain on market
Reason: Blood clotting time test results for these test tubes are typically shorter than expected resulting in the data being misinterpreted as meaning inadequate anticoagulation.

Product: AMBU, Adult Resuscitator, Mark II, with non-reservoir intake valve used for oxygen enrichment for life-saving emergency care, Recall #T-156-2
Code: Lot number on bag neck/box: 96201/VO-01, 96202/VO-02, 96203/OV-03, 96008/VO-11
Manufacturer: AMBU International, Copenhagen, Denmark
Recalled by: Narco Scientific, Air-Shields Division, Hatboro, Pennsylvania, by telephone, April 28, 1982 and follow-up letters, May 6, 1982 for lots VO-01 and VO-02 and May 21, 1982 for lots OV-03 and VO-11. Firm initiated recall
Distribution: Nationwide and South America
Size & Quantity: 705 units of the four lots were distributed
Reason: The molded rubber valve, where defective, does not allow oxygen to pass properly into the AMBU bag, making it impossible to ventilate the patient.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Progresso Italian Peeled Tomatoes, 14 ounces, packed 24 cans per case, Recall #F-222-2
Code: All codes
Manufacturer: Unknown
Recalled by: Winn-Dixie Stores, Inc., Raleigh, North Carolina (importer), by letter, April 21, 1982. Firm initiated recall complete
Distribution: North Carolina, Virginia
Size & Quantity: Firm estimates none remains on market
Reason: Hydrogen swells due to an apparent can lining failure. The Virginia Department of Agriculture requested that the firm remove all of this can code series.

Product: Triple Sulfa Liquid Cherry Flavor Oral Suspension, 16 ounce bottles, an Rx drug used in the treatment of chancroid, trachoma, inclusion conjunctivitis and nocardiosis, Recall #D-091-2

Code: Lot 22085 Exp. Jan 1984
Manufacturer: National Pharmaceutical Mfg. Co. Inc., Baltimore, Maryland
Recalled by: Manufacturer, by telephone, April 16, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 1,525 units were distributed
Reason: Some units did not have the lot number and expiration date on the product label.

Product: Dow Urea Nitrogen Reagent Set, which contains three components: Urea Nitrogen Reagent, 1875 ml., Urea Nitrogen Standard, 4 ml., Diacetylmonoxime Reagent, 100 ml, an In-vitro diagnostic test kit for the direct quantitative determination of urea nitrogen in serum plasma or urine, Recall #T-160-2
Code: The test kit label and the urea nitrogen reagent label are coded: lot number ZA3L/use before FEB 84. The other reagents in the kit have different lot numbers
Manufacturer: Dow Diagnostics, The Dow Chemical Company, Indianapolis, Indiana
Recalled by: Dow Chemical U.S.A., Indianapolis, Indiana, by telephone, May 11-12, 1982 and letter, May 11, 1982. Firm initiated recall
Distribution: Nationwide, Canada, Italy
Size & Quantity: 319 kits were distributed
Reason: Low absorbance reading for the urea nitrogen reagent component.

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NOTE: A portion of the May 26, 1982 Enforcement Report, printed and distributed in the New York area by the National Association of Retail Druggists, mistakenly listed Recall #D-086-2, Clindex Capsules, as a Class I recall instead of a Class III recall, which in fact it was. The official copy of the Enforcement Report, printed and distributed by FDA, properly listed it as a Class III recall.

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July 7, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	Lifeline Endotracheal Tube, oral murphy tip, Rx legend, used in the administration of anesthesia, it is also incorporated into CPR and Anaphylactic Shock Resuscitation Kits to provide an airway during resuscitation, Recall #T-144-2
Code:	All lots
Manufacturer:	Lifeline Products, Inc., Wheeling, Illinois
Recalled by:	Manufacturer, by telephone, May 6, 1982 and letter, May 13, 1982. Subrecalling firm is Bristol Laboratories, Syracuse, New York. The endotracheal tube is being subrecalled from the product, "Systematic Pulmono/Cardiac Anaphylaxis Resuscitation Kit (SPARK)" by the subrecaller. Firm initiated recall
Distribution:	Nationwide
Size & Quantity:	Approximately 17,000 endotracheal tubes were distributed
Reason:	Some endotracheal tubes have defective cuffs which leak air and have the potential of causing inadequate cuff sealing. Also, some uncuffed endotracheal tubes were labeled as cuffed.

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HE 20. 4039:

Product: Aspirin Tablets, 5 grain, USP, in 1000 tablet bottles, an OTC analgesic, Recall #D-093-2
COde: Lot #190581
Manufacturer: Superpharm Corporation, Central Islip, New York
Recalled by: Manufacturer, by letter dated June 18, 1982. Firm initiated recall
Distribution: The entire lot was shipped to Veterans Administration, Hines, Illinois
Size & Quantity: Firm estimates 100/1000 tablet bottles remain on market
Reason: A 1000 tablet bottle containing OTC diet tablets was mislabeled as "***Aspirin Tablets, USP, 5 Grains Each ***."

Product: Soft Mate Lens Care Starter Kit, a cold disinfection system consisting of a rinsing solution, disinfectant, and a sterile cleaning solution, Recall #T-157-2
Code: List #A917, lot #B52C
Manufacturer: Barnes-Hind Pharmaceuticals, Inc., Sunnyvale, California
Recalled by: Manufacturer, by telephone and letters, April 23 and 26, 1982. Firm initiated recall
Distrtibution: Nationwide and Puerto Rico
Size & Quantity: 4,432 kits were distributed
Reason: The disinfection and storage solution of the kit may contain a higher than normal level of surfactant (surface active agents).

Product: I.M.V. Set-Ups with Safety Valve, respiratory care products, packed in clear plastic bags, Recall #T-158-2
Code: Catalog number followed by lot number: 001700 - SE1105, OC1053, NO1088, JA2104, FE2109, AP2171; 001701 - SE1106, OC1065, OC1102, NO1099, JA2113, FE2107; 001702 - SE1098, OC1077, NO1077, JA2123, FE2102, MA2255
Manufacturer: Airlife Inc., Montclair, California
Recalled by: Manufacturer, by letter dated May 19, 1982. Firm initiated recall
Distribution: Nationwide, Australia, Canada
Size & Quantity: 3,502 cases (52,530 units) were distributed
Reason: Some of the one-way valves may not open due to a design defect in the method of assembly, which will block gas flow to the patient during spontaneous respiration.

Product: (a) DC-175 Synchronizer, used in DC-170 Defibrillator; (b) DC-195 Synchronizer, used in DC-190 Defibrillator; (c) CS-615 Monitor, used in DC-180 and DC-185 Defibrillators. Products (a) and (b) are electronic timers used to release the pulse of energy from the defibrillator at the proper point in the cardiac cycle; used in cardioversion procedures, these units are optional parts of the defibrillator. The monitor design includes a non-fade screen, freeze-frame capability and a rechargeable battery pack so that the unit is completely portable, Recall #T-179/180-2

Code: (a) all units; (b) serial numbers under 2011; (c) serial numbers under 2807

Manufacturer: The Burdick Corporation, Milton, Wisconsin

Recalled by: Manufacturer, by letter, April 6, 1982. Firm initiated recall

Distribution: Nationwide and international

Size & Quantity: Firm estimates approximately 2186 devices are involved

Reason: The devices allow isolation current to ground out when defibrillator paddles come in contact with the metal case or any grounded metal.

Product: CPI Insulin Pump Infusion Sets, Models 9120 and 9121, Recall #T-181-2

Code: Lot numbers 202050 and 202051

Manufacturer: Norton Company, Akron, Ohio

Recalled by: CPI, St. Paul, Minnesota (distributor), by letter, June 2, 1982. Firm initiated recall

Distribution: Nationwide, Canada, international

Size & Quantity: 8940 sets were shipped

Reason: Potential cracking of infusion tubing where tubing connects to luer lock.

Product: Sterile Disposable Vacuum Curette, used for scraping and then removing endometrial tissue from the womb, Recall #T-182-2

Code: All codes

Manufacturer: Poly-Med, Inc., Cockeysville, Maryland

Recalled by: Manufacturer, by telephone, on or about April 26, 1982. Firm initiated recall

Distribution: Washington, D.C., Pennsylvania, Utah, Illinois, Minnesota

Size & Quantity: 6,890 units were distributed during January 1982 through April 1982

Reason: There is no assurance of sterility of the device because of Good Manufacturing Practice deficiencies in the sterilization operation. The device labeling does not contain the name and place of the manufacturer or the established, common or usual name of the device.

Product: Cardiovascular Catheters, including aortographic, ventricular cardiac and selective catheters, manufactured from white polyethylene, Recall #T-185-2

Code: All lot numbers of white polyethylene catheters manufactured from 1974 to February 1980
Manufacturer: Universal Medical Instrument Corporation, Ballston Spa, New York
Recalled by: Manufacturer, by letters and mailgrams, April 7 and 19, 1982 and May 28, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: Firm estimates 250,000 catheters were distributed from 1974 through February 1980
Reason: The catheter breaks and/or fractures during use.

Product: Source Plasma (Human), an extension of Recall #B-018-2 which originally appeared on the April 14, 1982 Enforcement Report
Code: 543848, 545481, 534049, 534805, 536296
Manufacturer: Plasma Services of San Antonio I, San Antonio, Texas
Recalled by: Plasma Services, Division of Blood Systems, Inc., Scottsdale, Arizona, by letter, April 27, 1982. Firm initiated recall
Distribution: Austria and West Germany
Size & Quantity: Five units are involved
Reason: The products distributed were collected from donor who previously tested HBsAg reactive; or were untested for HBsAg.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Sodium Fluoride Tablets, USP, 2.2 mg. an oral single ingredient prescription drug used as a supplement for control of dental caries in children, Recall #D-092-2
Code: Control #103074, EXP 4/83
Manufacturer: Chelsea Laboratories, Inc., Inwood, New York
Recalled by: Manufacturer, by memo dated December 16, 1981. Firm initiated recall complete
Distribution: The entire lot was shipped to one consignee in New York
Size & Quantity: FDA estimates less than 10 percent remains on market
Reason: Subpotent for sodium fluoride.

Product: Cordis Percutaneous Entry Tray for percutaneous catheter introduction, Recall #T-186-2
Code: Catalog #501-638; lot #3022814, 3022817
Manufacturer: Cordis Corporation, Miami, Florida
Recalled by: Manufacturer, by letter, May 26, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 1280 trays were distributed
Reason: Some users had difficulty inserting the vessel dilator into the catheter sheath because of the lack of lubricant in some of the hemostasis valves.

Product:	Gordon Donmichael Esophageal (Gastric Tube) Airway EGTA Kit consisting of face mask, face mask cuff, esophageal tube, one-way valve, syringe and gastric tube, used for artificial ventilation or cardiopulmonary resuscitation, one kit per carton, Recall #T-190-2
Code:	Lot numbers 8049, 8060, 2273 through 2341, 2361 through 2364, B024 through B028, B041 through B044, B053, B054, B057, B069, B073, B139, B142, B145, B151
Manufacturer:	Brunswick Manufacturing Company, Inc., Quincy, Massachusetts
Recalled by:	Manufacturer, by letter, June 4, 1982. Firm initiated recall
Distribution:	Nationwide, Canada
Size & Quantity:	16,240 kits were distributed
Reason:	Carton labeling contains instructions for use of the esophageal (obturator) airway instead of instructions for use of the esophageal (gastric tube) airway.

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

July 14, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	(a) Cardioplegia Solution Administration System, model numbers CAS-6, CAS-6V, CAS-12, CAS-12V; (b) Cardioplegia Cooling Administration System, model numbers CCAS; (c) Custom Pac with a Hydrophobic/Hydrophilic Cardioplegia Filter, Recall #T-187/189-2
Code:	(a) all lots; (b) all lots; (c) no model or lot numbers specified
Manufacturer:	Bentley Laboratories Inc., Irvine, California
Recalled by:	Manufacturer, by letters dated May 17, 1982 and telex, May 19, 1982. Firm initiated recall
Distribution:	Nationwide and international
Size & Quantity:	(a) 4,900; (b) 11,800; (c) 5,800 units were distributed
Reason:	Degradation of the hydrophobic membrane, resulting in enlarged pore size, allows the passage of air bubbles downstream to the patient.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product:	Promethazine Expectorant-Plain, 5 ml. unit dose, 10/5 ml. cups per tray, 10 trays/case, Recall #D-094-2
Code:	Lot #2A09
Manufacturer:	Pharmaceutical Associates, Inc., Conestee, South Carolina

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HE 20. 4039:

Recalled by: Manufacturer, by letter, June 10, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 402 cases were distributed and firm estimates 50 percent remains on market
Reason: Four trays of 10/15 ml. cups of Docusate Sodium with Casanthranol were found in a case with six trays of Promethazine Expectorant-Plain. The four trays of Docusate Sodium with Casanthranol contained package inserts for Promethazine Expectorant-Plain. The individual unit dose cups were labeled correctly.

Product: Mrs. Weiss Brand: Kluski Egg Noodles, Spinach Egg Noodles, Extra Fine Egg Noodles, Medium Egg Noodles, Wide Egg Noodles, Haluska Noodles; Ippolito's Ideal Brand: Fine Egg Noodles, Medium Egg Noodles, Wide Egg Noodles, Extra Wide Egg Noodles, Recall #F-223/230-2
Code: 5102, 5112, 5122, 5132, 5142, 5172, 5192, 5212
Manufacturer: Weiss Noodle Company, Solon, Ohio
Recalled by: Manufacturer, by telephone starting June 9, 1982. Notices were mailed June 11, 1982. Firm initiated recall
Distribution: Ohio, Michigan, Kentucky
Size & Quantity: Approximately 2800 cartons (10 pounds or 15 pounds) were distributed
Reason: Insect infestation in manufacturing plant.

Product: Generic Apple Juice from Concentrate, 64 fluid ounce glass bottles, 6 bottles per case, Recall #F-231-2
Code: All products produced between January 15, 1982 and May 3, 1982. Lot numbers 0152C12 through 1162C12 and 1132CH through 1232CH.
Manufacturer: Wagner Juice Company, subsidiary of Westin, Inc., Cicero, Illinois and Food Processors, Chattanooga, Tennessee, (co-packer)
Recalled by: Wagner Juice Company, subsidiary of Westin, Inc., Cicero, Illinois, by teletype and letter, June 24, 1982. Firm initiated recall
Distribution: Mississippi, Alabama, Kentucky, North Dakota, Michigan, Wisconsin, Missouri, Tennessee
Size & Quantity: Firm estimates 5,000 cases of 6 bottles each remain on the market
Reason: Product contains beet sugar which is not declared in the list of ingredients.

Product: Rex Brand Whole Sesame Seed, packaged in 1-1/2 ounce glass jars, 48 jars per case, Recall #F-232-2
Code: Not coded
Manufacturer: Rex Pure Foods, Inc., New Orleans, Louisiana
Recalled by: Manufacturer, by telephone, June 4, 1982. Firm initiated recall complete
Distribution: New Orleans, Louisiana
Size & Quantity: Firm estimates none remains on market
Reason: Adulterated with insect filth.

Product: Recleaned Natural Sesame Seed in 50 pound bags, Recall #F-233-2
Code: Lot #2882
Manufacturer: Sesame Products, Inc., Paris, Texas
Recalled by: Manufacturer, by telephone, June 23, 1982. Firm initiated recall complete

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Distribution: Arkansas, Illinois, Michigan, Ohio, Oregon, Wisconsin
Size & Quantity: Firm estimates none remains on market
Reason: Adulterated with insect excreta.

Product: De Jean's brand shrimp, regular pack, drained weight 4-1/2 ounces in 2 piece aluminum cans: (a) Jumbo Shrimp; (b) Large Shrimp; (c) Medium Shrimp; (d) Small Shrimp; (e) Tiny Cocktail Shrimp; (f) Broken Shrimp, Recall #F-239-2
Code: All production with a two line code with a bottom line #D1461
Manufacturer: De Jean Packing Company, Biloxi, Mississippi
Recalled by: Manufacturer, by telephone, April 1, 1982 and June 18, 1982. Firm initiated recall
Distribution: Alabama, Florida, North Carolina, Texas, Michigan, Pennsylvania, New York, Washington State, Puerto Rico, Canada
Size & Quantity: Firm estimates none remains on market
Reason: Decomposition.

Product: Je Reviens Brand Cologne Spray in 60 ml. 2 fluid ounce glass bottles, labeled Eau De Cologne, Parfums Worth, Paris, France, Recall #F-240-2
Code: Catalog #8 1581 on the box. No lot numbers
Manufacturer: Parfums Worth, Paris, France
Recalled by: Original World Wide Ltd., Inc., Miami, Florida (importer), by letter, June 15, 1982. Firm initiated recall
Distribution: California, Texas, Florida, Pennsylvania, New York, New Jersey, Maryland, Massachusetts, Georgia, Ohio
Size & Quantity: 100 units were distributed
Reason: Product is labeled containing propellant 114, a chlorofluorocarbon prohibited in cosmetics.

Product: Amersham Vitamin B12/Folate Dual Radioassay Kit, an in-vitro diagnostic used to measure serum levels of Vitamin B12 and folate to determine the cause of megaloblastic anemia, 100 test kits and 200 test kits, Recall #T-191-2
Code: 100 test kit catalog #C.T. 301, lot numbers 13A, 14A, 15; 200 test kit catalog number C.T. 302, lot numbers 13, 13A, 14, 15, 16
Manufacturer: Amersham International Limited, Buckinghamshire, England
Recalled by: Amersham Corporation, Arlington Heights, Illinois, by telephone, May 25, 1982 with follow-up letter, May 26, 1982. Firm initiated recall
Distribution: Nationwide, Canada
Size & Quantity: Firm estimates 259/100 test kits and 111/200 test kits remain on market
Reason: Potential instability of the folate standards under present recommended refrigeration storage conditions and user handling after reconstitution.

Product: Technicon TQC Hematology Calibrator for Platelets, for in-vitro diagnostic use as a dilution control for verifying the calibration of platelet channels on Technicon Hemalog and Autocounter systems; and is used to monitor valve drift due to dilution variation during high volume use after primary calibration, packed in 10 x 10 ml. vials, Recall #T-192-2

Code: Product #T03-0946, lot numbers B1F407, B1G510, B1G547
Manufacturer: Technicon Instruments Corporation, Middletown, Virginia
Recalled by: Technicon Instruments Corporation, Tarrytown, New York, by mailgrams, February 18, 1982. Firm initiated recall complete
Distribution: Unknown
Size & Quantity: Firm estimates over 90 percent of the stock has been used up
Reason: There was a discrepancy in the original values assigned to the subject lots. The original values have been revised.

Seizure Actions Filed:

Product: Methenamine Tablets (82-165-634)
Charge: Adulterated - Product is a new animal drug without an approved New Animal Drug Application; Misbranded - Labeling fails to bear adequate directions for use
Firm: Tendene Division, Lee Drug Company, Omaha, Nebraska
Filed: June 25, 1982 - U.S. District Court for the District of Nebraska at Omaha; Civil #CV 82-0-306, FDC #63732.

Note:

Apple Juice in 46 ounce cans, Recall #F-196-2,which appeared on the June 9, 1982 Enforcement Report as a Class III, has been extended to include the entire 1979 and 1980 packs and juice produced in February 1981.

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FDA Enforcement Report

Press Office
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July 21, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	LI-2, APP-A, APP-B, LI-4, ARCOlith-5, ARCOlith-6, ARCOlith-7, ARCOlith-9, ARCOlith-10, ARCOlith-12, ARCOlith-2000, ARCOlith-2100, ARCOlith-3000, ARCOlith-3001, ARCOlith-3020, cardiac pulse generators (pacemakers) which are powered by thionyl chloride batteries, Recall #T-163/177-2
Code:	All serial numbers of all models
Manufacturer:	ARCO Medical Products, Subsidiary of Atlantic-Richfield Company, Leechburg, Pennsylvania
Recalled by:	Intermedics, Inc., Freeport, Texas, by "Dear Doctor" letters dated May 7, 1982. Firm initiated field correction
Distribution:	Nationwide, W. Germany, Italy, Japan, The Netherlands, Switzerland, Norway, Ireland, Venezuela, Chile, Spain, Austria, Republic of China, Taiwan, Morocco
Size & Quantity:	Firm estimates 3035 units (inclusive of all models) of domestic accounts remain implanted to date and 3389 units (inclusive of all models) of international accounts remain implanted to date
Reason:	Some pacemakers may exhibit an unacceptable high incidence of depletion without adequate end-of-service warning and/or sudden loss of output.

HE 20. 4039:

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Chikara Brand Oriental Style Noodles in hermetically sealed plastic bags, 7.25 ounces and 21.75 ounces, Recall #F-241-2
Code: Product is not coded; all packages are under recall
Manufacturer: Sakura Noodle Company, Los Angeles, California
Recalled by: Manufacturer and Sisco Food Company, Gardena, California (distributor), by telephone with follow-up letter, July 1, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates 6,870 cartons of 30 packages each remain on market
Reason: Product is a low acid canned food in hermetically sealed containers. Process and storage conditions for the product will not prevent the growth of Clostridium botulinum. The process for the product is not on file with FDA as required by 21 CFR Part 108.35.

Product: Healthdyne Power Pack, Recall #T-193-2
Code: Catalog number 150
Manufacturer: Healthdyne, Inc., Marietta, Georgia
Recalled by: Manufacturer, by letters, February 16, 1982, to firm's international distributors and May 27, 1982, to all domestic accounts. Letters contain procedure to test for proper calibration. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: Firm estimates 178 units remain on market
Reason: The power packs' indicator lights may have been miscalibrated which could lead the user into thinking that the battery is fully charged when, in reality, it is not.

Product: "Marx O2" Respiratory Support System, Model 650-DT Oxygen Concentrator with Thomas Compressor, Models 2907-CA22 and 2908-CA22, an oxygen concentration system, using room air as its source to deliver a continuous, concentrated supply of oxygen; oxygen is concentrated to 95 percent at 2 liters per minute. The unit is used to provide increased oxygen levels to home patients with chronic lung problems or congestive heart failure, an Rx device, Recall #T-194-2
Code: Serial numbers 2360, 2365, 2366, 2368-2377, 2380-2388, 2390, 2393-2408, 2410, 2411, 2413-2422, 2424, 2426, 2427, 2429-2435, 2437-2439, 2442, 2444-2450,
Manufacturer: Marx Medical, Inc., Taylor, Michigan (compressor manufacturer: Thomas Industries, Sheboygan, Wisc.)
Recalled by: Manufacturer, by letters, June 4, 1982 through June 17, 1982. Firm initiated recall

Distribution:	Nationwide
Size & Quantity:	72 units are subject to recall
Reason:	Fatigue cracks in the compressor exhaust reed valves may cause a decrease in oxygen concentration.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product:	Nubain Injection, 10 mg./ml. in 2 ml. ampules, an Rx drug used as an analgesic, Recall #D-095-2
Code:	Lot #SB077D, EXP 2/85
Manufacturer:	Endo Laboratories, Inc., Garden City, New York
Recalled by:	Manufacturer, by telephone, June 28, 1982. Firm initiated recall
Distribution:	Nationwide
Size & Quantity:	1,000 boxes of 10 ampuls were distributed
Reason:	Product intended for export to Canada was shipped in domestic channels. The product and dosage is the same as the domestic product; however, the labeling is different in that it does not have an Rx legend or an NDC number.

Product:	Heyer-Schulte Suction Reservoir Kit, 100 cc reservoir with flat suction drain 3/4 length perforation, 7 mm x 100 cm long, Recall #T-178-2
Code:	Lot numbers 218805 and 218806, catalog #SU130-1348
Manufacturer:	American Heyer-Schulte Corporation, Goleta, California
Recalled by:	Manufacturer, by letter dated May 21, 1982, instructing consignees to check stock and return any of the recalled product. Firm initiated recall
Distribution:	Nationwide and UK
Size & Quantity:	Firm estimates 70 kits remain on market
Reason:	The kit may contain a drain with full length perforation rather than 3/4 length perforation.

Seizure Actions Filed:

Product:	Myco Triacet Cream (82-312-205/206)
Charge:	Adulterated - Product not manufactured in conformance with current Good Manufacturing Practice regulations
Firm:	Lemmon Company, South Hackensack, New Jersey
Filed:	June 17, 1982 - U.S. District Court for the Western District of New York at Buffalo; Civil #82-523, FDC #63728.

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July 28, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	Puritan-Bennett Tubing Connector Kit, sold as a component part of the SA-3 Spirometer Alarm, an alarm device used with life-sustaining ventilator systems, Recall #T-183-2
Code:	Tubing connector kit part #015485 and part #015460 (SA-3 monitoring spirometer assembly in which the tubing connector kit has been attached to the spirometer assembly), lot numbers for the tubing connector are: AAA, AAB, AAC, AAE, AAF, AAG, AAH, AAJ, AAK, AAL, AAM, AAN, AAP
Manufacturer:	Puritan-Bennett Corporation of California, Los Angeles, California
Recalled by:	Manufacturer, by letter, on or about May 7, 1982. Firm initiated recall
Distribution:	Nationwide and international
Size & Quantity:	7,118 tubing connector kits were distributed from February 1, 1981 to March 30, 1982
Reason:	The tubing connector kit may be incorrectly assembled, which can cause the alarm not to activate if a disconnect should occur at the exhalation valve inlet of a ventilator.

HE 20.4039:

Product: B-D Drake Willock Model 7620 Blood Line Clamp for use with B-D Drake Willock Brand Hemodialysis Units, Recall #T-184-2
Code: Units with serial numbers between 700-1449 and 2601-2937
Manufacturer: B-D Drake Willock, Portland, Oregon
Recalled by: Manufacturer, by letter, April 1981 and telephone, May 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: Firm estimates 450 units subject to recall
Reason: The electrical connected device could malfunction, resulting in the inability to reset a machine alarm which could result in the line clamp remaining reset, overriding any alarm condition.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Model LP4 Portable Volume Ventilator with Control, Assist-Control and Intermittent Mandatory Ventilation capabilities, Recall #T-197-2
Code: All serial numbers (0434 through 1017)
Manufacturer: Life Products, Inc., Boulder, Colorado
Recalled by: Manufacturer, by letters, June 1, June 16, June 20, 1982. Firm initiated recall
Distribution: Nationwide, India, Australia
Size & Quantity: Firm estimates 520 units are in commerce
Reason: A defective miniature relay on the "B" circuit board may stick temporarily causing the ventilator to not start up or to stop cycling during operation thus sounding the low pressure alarm.

Product: General Electric computed tomography device, CT/T 7800, 7805 and 8800 systems, Recall #R-015-2
Code: Model numbers 46-186550G3 X-ray controls, 46-186550G4 X-ray controls below serial number 20858CN7; except 46-186550G3 S/N 1360/CNO, 16241CN2, 16242CNO, 17284CN3, 17644CN6, 18226CN1; 46-186550G4 S/N 17656CNO
Manufacturer: General Electric Company, Medical Systems Division, Milwaukee, Wisconsin
Recalled by: Manufacturer. FDA approved the firm's corrective action plan by letter, April 30, 1982. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: 800 units have been produced

Reason: Systems are defective under the Radiation Control for Health and Safety Act of 1968 in that they emit electronic product radiation unnecessary to the accomplishment of the primary purpose which creates a risk of injury. The systems are defective in that, if the X-ray target is heated beyond its ratings, the tube enclosure may, under extreme circumstances, rupture causing unnecessary patient radiation.

Product: Laakmann's CO2 Lasers with RF-100 power supplies, used for general and research purposes, Recall #R-017-2

Code: Products shipped prior to November 30, 1981

Manufacturer: Laakmann Electro-Optics, Inc., San Juan Capistrano, California

Recalled by: Manufacturer. FDA approved the firm's corrective action plan by letter, May 7, 1982. Firm initiated field correction

Distribution: Unknown

Size & Quantity: 27 units had been introduced into commerce prior to November 30, 1981

Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968 in that the products lacked an adequate remote control connector.

Product: Davidson Optronics laser products, Recall #R-018-2

Code: Models D305L, D319, and 105-2686

Manufacturer: Davidson Optronics, Inc., West Covina, California

Recalled by: Manufacturer. FDA approved the firm's corrective action plan by letter, June 8, 1982. Firm initiated field correction

Distribution: New York, Arizona, Iowa, California, Texas, Colorado

Size & Quantity: Seven products have been introduced into commerce

Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968 in that all models lacked certification and identification labels; lacked the appropriate warning logotype, aperture label, and noninterlocked housing labels; and eyepiece filters which are required to assure that only Class I levels of laser radiation are accessible through the viewing optics.

Product: Various Class I laser tools which incorporate solid state lasers and connected work stations, Recall #R-019-2

Code: Various codes

Manufacturer: Control Laser Corporation, Orlando, Florida

Recalled by: Manufacturer. FDA has approved the firm's corrective action plan. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: 15 uncorrected units remain in the possession of users
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Numorphan (Oxymorphone HCl) Injection, an Rx narcotic analgesic administered parenterally, in 10 ml. multiple dose vials, 1.5 mg./ml., packed in individual shelf cartons, 100 units per shipping case, Recall #D-096-2
Code: Lot number "MSB510C" EXP 2/85
Manufacturer: Endo Pharmaceuticals, Inc., Manati, Puerto Rico
Recalled by: Manufacturer, by "Product Correction" letter on or about July 27, 1982. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: 3,452 vials were distributed
Reason: The manufacturing firm inadvertently labeled the product with a 36 month expiration date instead of the correct 24 month expiration date.

Product: Chlorpheniramine Maleate 4 mg., compressed tablets, an OTC antihistamine for temporary relief of hay fever and upper respiratory allergies, unit bottle size 1000 tablets, Recall #D-097-2
Code: Control #33718, EXP 10/84
Manufacturer: Tablicaps, Inc., Franklinville, New Jersey
Recalled by: Manufacturer, by telephone on or about June 16, 1982 with follow-up letter dated June 23, 1982. Firm initiated recall
Distribution: One own label distributor in Philadelphia, Pennsylvania
Size & Quantity: 936 bottles of 1000 tablets were distributed
Reason: Product fails USP disintegration test.

Product: Antispasmodic Compressed Tablets, an oral Rx anticholinergic/antispasmodic with sedative action containing phenobarbital 16.2 mg; scopolamine hydrobromide 0.0065 mg; atropine sulfate 0.0194 mg, and hyoscyamine sulfate 0.1037 mg, packed in unit bottles of 5,000, Recall #D-098-2
Code: Control #33774; EXP 11/83
Manufacturer: Tablicaps, Inc., Franklinville, New Jersey
Recalled by: Manufacturer, by telephone on or about June 16, 1982 with follow-up letter dated June 23, 1982. Firm initiated recall

Distribution: One own label distributor in New Britain, Connecticut
Size & Quantity: 249 bottles of 5,000 were distributed
Reason: Product fails to meet USP requirements for weight variation.

Product: (a) Rainbow Light brand 100 percent Pure Mexican Spirulina, 500 mg., 100 and 200 tablet bottles; (b) Rainbow Light brand Herbal Diet and Cleansing Formula, 1000 mg., 240 tablet bottles, Recall #F-242/243-2
Code: Lot numbers 25 and 29
Manufacturer: Spirulina powder was received in bulk from Mexico and tableted by Nevada Nutritional, Hayward, California
Recalled by: Rainbow Light Trading Company, Sandpoint, Idaho, by letter, on or about July 1, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 523,000/500 mg. and 188,000/1000 mg. tablets were distributed
Reason: Adulterated with insect fragments.

Product: "Marx O2" Respiratory Support System, Model 650-DT Oxygen Concentrator with a Thomas Compressor, Model 2917CM22-778, used to provide increased oxygen levels to home patients with chronic lung problems or congestive heart failure, Recall #T-195-2
Code: Serial #'s 2359 thru 4482 sequentially. Not all units between these numbers are under recall, 303 units have been identified as being retrofitted after the first recall, 3 test units were never sold, 6 units were never manufactured, and 20 units were scrapped
Manufacturer: Marx Medical Inc., Taylor, Michigan
Recalled by: Manufacturer, by letters sent June 4, 16, or 17, 1982. Firm initiated recall
Distribution: Nationwide and Canada
Size & Quantity: 1,782 units are subject to recall
Reason: The plastic cooling fan may become loose and result in compressor failure due to the lack of cooling action.

Product: Gelman Drug Standard Set, 3 x 2.0 ml., for use in thin layer chromatography. Set contains 3.0 mg./ml. of each of the following in absolute methanol: Drug Standard Group I - Acidic Drugs; Drug Standard Group II - Basic Drugs; Drug Standard Group III - Basic Drugs. Product is an in-vitro diagnostic for determining the presence of specific drug substances in urine, Recall #T-196-2
Code: Product No. 51910, lot #4891 EXP 10/82
Manufacturer: Gelman Sciences, Inc., Ann Arbor, Michigan

Recalled by: Manufacturer, by letters sent March 24, 1982 and a second letter on April 8, 1982 to non-respondents. Firm initiated recall
Distribution: Nationwide, Mexico, Australia
Size & Quantity: Approximately 150 sets remain on market
Reason: Some drug standard vials may be mislabeled.

Seizure Actions Filed:

Product: Fruit Cocktail (82-341-470)
Charge: Adulterated - Swollen cans
Firm: Pacific Coast Producers, Oroville, California
Filed: June 29, 1982 - U.S. District Court for the Eastern District of Arkansas; Civil #LR-M-499, FDC #63737.

Product: Cough Syrup (82-287-133)
Charge: Adulterated - Product was introduced into interstate commerce without an approved New Drug Application; Misbranded - Product's labeling falsely represents and suggests the drug contains specific amounts of chloroform which representation and suggestion are contrary to fact because chloroform is not present
Firm: Around the World Merchandisers, Inc., Linden, New Jersey
Filed: July 13, 1982 - U.S. District Court for the District of New Jersey at Newark; Civil #82-2242, FDC #63733.

Product: Multiple Foods (82-283-865)
Charge: Adulterated - Certain of the articles of food consist in part of a filthy substance such as rodent excreta pellets and bird excreta; and all of the articles of food have been held under insanitary conditions whereby they may have become contaminated with filth
Firm: Crook Produce Company, Beckley, West Virginia
Filed: July 14, 1982 - U.S. District Court for the Southern District of West Virginia at Charleston; Civil #82-5138, FDC #63739.

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August 4, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	(a) Refecto Cil Permanent Cream Dye for Eyelashes and Eyebrows - Brown; (b) Refecto Cil Permanent Cream Dye for Eyelashes and Eyebrows - Blue/Black; (c) Refecto Cil Permanent Cream Dye for Eyelashes and Eyebrows - Black; (d) Refecto Cil Permanent Cream Dye for Eyelashes and Eyebrows - Graphite, Recall #F-244/247-2
Manufacturer:	Gschwentner-Haarkosmetik, Vienna, Austria
Recalled by:	Odette De Paris, Tarzana, California (importer/distributor), by letter, July 20, 1982. Firm initiated recall. See FDA press release P82-34, July 30, 1982
Distribution:	California, Pennsylvania, Michigan
Size & Quantity:	1,005 1/2 oz. tubes, and 137 1/6 oz. tubes were distributed
Reason:	Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

NONE

HE20.4039:

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Torigian brand of Niacin Injection USP, 1 gm./10 ml., 10 ml., single use vial, an Rx drug used as a nutritional injectable for vitamin deficiency, Recall #D-099-2
Code: Lot #81234
Manufacturer: Torigian Laboratories, Inc., Queens Village, New York
Recalled by: Manufacturer, by telephone, July 12, 1982. Firm initiated recall complete
Distribution: Two consignees in New York and California
Size & Quantity: Firm estimates none remains on market
Reason: Firm does not have an approved New Drug Application and lacks stability data to support the 36 month expiration date.

Product: Orex Saliva Substitute, an OTC oral spray used for dry mouth, packaged in a 6 fluid ounce (180 cc) plastic bottle labeled to contain 2 ppm sodium fluoride. The bottle is shrinkwrapped, Recall #D-100-2
Code: 058201
Manufacturer: Young Dental Manufacturing Company, Inc., Brownsville, Texas
Recalled by: Young Dental Manufacturing Company, Inc., Maryland Heights, Missouri, by telephone, July, 15, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 411 six fluid ounce bottles were distributed
Reason: Misformulation. The subject batch contains 2000 ppm fluoride rather than 2 ppm.

####

Note: Recall #R-015-2, which appeared on the Enforcement Report of July 28, 1982 as a Class II, should be corrected to read: Code: Model numbers 46-186550G3 X-ray controls, 46-186550G4 X-ray controls below serial number 20858CN7; except 46-186550G3 S/N 13601CN0, 16241CN2, 16242CN0, 17284CN3, 17644CN6, 18226CN1; 46-186550G4 S/N 17656CN0

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August 11, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Petro-syllium No. 2 with Phenolphthalein in 16 ounce (1 pint) bottles, a psyllium emulsion which is taken orally as a laxative, for relief of constipation, an OTC drug, Recall #D-101-2
Code:	Lot #1 H20 EXP dates 5/85 and 5/86
Manufacturer:	Ayerst Laboratories, Division of American Home Products Corporation, Rouses Point, New York
Recalled by:	Whitehall Laboratories, Division of American Home Products Corporation, New York, New York, by letter, July 7, 1982. Firm initiated recall
Distribution:	Nationwide
Size & Quantity:	Firm estimates 3,019 bottles were distributed
Reason:	The firm found some samples contained non-speciated yeast and mold as well as Pseudemonas cepacia.

HE 20.4039:

Product: Polycillin-N (sterile ampicillin sodium), for intramuscular or intravenous injection, 500 mg. vials, shrinkwrapped in units of 10, Recall #D-103-2
Code: Lot #L1M36, EXP 11/85
Manufacturer: Bristol Alpha Corporation, Division of Bristol-Myers Company, Barceloneta, Puerto Rico
Recalled by: Bristol Laboratories, Division of Bristol-Myers Company, Syracuse, New York, by letter, July 19, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 28,879 units of 10 vials each were distributed and approximately 50 percent remains on market
Reason: Mislabeled. Some units of 10 bear shrinkwrap labels for the two gram potency of the same product.

Product: "Young Look Moisturizing Lotion" - a powder packed lotion in a 2 fluid ounce glass bottle with a metal screw on cap. This lotion is applied to the face prior to applying make-up, Recall #F-249-2
Code: None
Manufacturer: Clay Park Labs, Ltd., Bronx, New York
Recalled by: Cosmetic Labs, Ltd., New York, New York, by letter during the week of July 26, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates 500 to 1000 units remain on market
Reason: Analysis revealed gram negative rods which were identified as CDC Group VE-2 bacteria. Additionally, labeling lacks the name and address of a responsible party.

Product: Pulsar, 4 Portable Cardioresuscitation System, Model numbers 2700, 2701, 2700A, 2701A. The system is composed of two or three components: Strip Chart Recorder, Model 3018, which is not found in the 2700 and 2700A models; a monitor scope (oscilloscope), model 1218/1218A; and defibrillator, model 2018, Recall #T-198-2
Code: All serial numbers of each model distributed prior to May 1, 1982
Manufacturer: Picker International Inc., Bedford, Massachusetts
Recalled by: Manufacturer, by letter dated April 15, 1982. Firm initiated field correction
Distribution: Nationwide, Canada, England, Hong Kong, Japan
Size & Quantity: 2235 units were distributed. All units remain on market
Reason: Patient's QRS waveform will not be displayed on the Model 1218 monitor in the Pulsar 4 system if the monitor is not properly seated.

Product: Hirsch Bipolar Forceps, 25 cm and 40 cm length, used for female sterilization by coagulating the fallopian tubes with an electric current during a laproscopic procedure, Recall #T-200-2
Code: Model #05126 (40 cm length), Model #05127 (25 cm length). All are under recall
Manufacturer: Martin Company, Tutilingen, West Germany
Recalled by: Olympus Corporation of America, Medical Instrument Division, New Hyde Park, New York (importer), by telephone, with follow-up letters to all customers dated June 21, 1982. Firm initiated recall
Distribution: Nationwide, Canada
Size & Quantity: Approximately 70 units were distributed
Reason: Jaws of the forceps may break during surgical procedure.

Product: Tomac Wet Dressing Pack with Saline Solution, catalog #23240-101 sterile. Each kit contains two 8"x4" 12-ply gauze sponges saturated with isotonic saline solution, used as a hot wet pack for stimulating blood flow, softening dry skin, scabs, or exudate; as a cold wet pack to control hemorrhaging, and provide relief of sprains, contusions, minor burns and also for cleansing in the nursery, Recall #T-201-2
Code: Sterilization #021082, lot #'s 0412, 0422, 0432, 0462, 0472; sterilization #021982, lot #'s 0502, 0532, 0542, 0552
Manufacturer: W.G. Whitney Corporation, Glenview, Illinois
Recalled by: Manufacturer, by letter, July 12, 1982 and subrecalled by American Hospital Supply, Division of American Hospital Supply Corporation, McGaw Park, Illinois, by letter, July 14, 1982. Firm initiated recall
Distribution: Nationwide, Canada
Size & Quantity: Firm estimates less than 90/100 pack cases remain on market
Reason: Product may have pathogenic mold growth rendering it non-sterile.

Product:
(a) Carolina Brand, 4"x4" 8-ply Sterile Gauze Sponges (2/pkg);
(b) Carolina Brand, 4"x4" 12-ply Sterile Gauze Sponges (2/pkg);
(c) Carolina Brand, 4"x4" 16-ply Sterile Gauze Sponges (2/pkg);
(d) Krest Brand, 4"x3" Sterile Krest Post-Operative Sponges (2/pkg);
(e) Krest Brand, 4"x4" Sterile Krest Post-Operative Sponges (2/pkg);
(f) Carolina Brand, 2"x2" Sterile 12-ply Gauze Sponges (2/pkg), Recall #T-202-2
Code: (a) Product code 31-2502, lot #'s 1413, 1414, 1415, 1426, 1427; (b) product code 31-2902, lot #'s 1416, 1417; (c) product code 31-2602, lot #'s 1420, 1421; (d) product code 31-8402, lot #1424; (e) product code 31-8502, lot #1425; (f) product code 31-2202, lot #1389
Manufacturer: Barnhardt Manufacturing Company, Inc., doing business as Carolina Absorbent Cotton Company, Charlotte, North Carolina

Recalled by: Manufacturer, by letter, July 7, 1982 and extended on July 20, 1982. Firm initiated recall

Distribution: Georgia, Michigan, Massachusetts, North Carolina, Pennsylvania, Virginia, Texas, Vermont, South Carolina, Delaware, Illinois, Alabama, Rhode Island, New York

Size & Quantity: (a) 120 cases/24 trays/25 envelopes; (b) 21 cases/24 trays/25 envelopes; (c) 42 cases/24 trays/25 envelopes; (d) 16 cases/24 trays/25 envelopes; (e) 24 cases/24 trays/25 envelopes; (f) 26 cases/30 boxes/50 envelopes were distributed. Firm estimates 80 percent remains on market

Reason: Sterility is compromised due to defective packaging.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Canned Sweet Potatoes, small whole southern yams in 9 ounce and 17 ounce cans, Recall #F-248-2

Code: Nine ounce can codes: 1762A/SW 320, 323, 330, 334; 17 ounce can code: 1762A/SW 348

Manufacturer: Bruce Foods, New Iberia, Louisiana

Recalled by: S&W Fine Foods, Inc., San Mateo, California, by letters, July 16, 1981 and March 22, 1982. Firm initiated recall

Distribution: New York, California, Illinois, Iowa, Kentucky, Michigan, Missouri, Ohio, Oklahoma, Tennessee, Wisconsin

Size & Quantity: Firm estimates none of the nine ounce cans remains on market and approximately 360 cases of the 17 ounce cans were distributed

Reason: Swollen cans.

Seizure Actions Filed:

Product: In-shell Peanuts (82-339-103)

Charge: Adulterated - Products have been held under insanitary conditions whereby they may have become contaminated with filth

Firm: Hancock Peanut Company, Inc., Courtland, Virginia

Filed: July 22, 1982 - U.S. District Court for the Eastern District of Virginia at Norfolk; Civil #82-526-N, FDC #63740.

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August 18, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	Heart*Aid Cardiac Resuscitator Model 60, designed to provide defibrillating or pacing impulses to restore normal heartbeat and breathing to an unconscious cardiac arrested patient, Recall #T-159-2
Code:	Units with serial numbers between 26000 and 26335
Manufacturer:	Cardiac Resuscitator Corporation, Lake Oswego, Oregon
Recalled by:	Manufacturer, by letter, March 1982 requesting return of device for retrofit. Firm initiated recall
Distribution:	Nationwide and international
Size & Quantity:	170 units were distributed
Reason:	Unit could erroneously double count some ECG waveforms which will automatically administer an untimely defibrillation shock.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Sarns 3/8 Inch Temperature Probe Connector, used in perfusion sets to provide an external connection of a temperature probe for monitoring blood temperatures, Recall #T-199-2

HE 20. 4039:

Code: Part #12189010, lot #'s: 810221967, 810421993, 811122090
Manufacturer: Sarns, Inc., Ann Arbor, Michigan
Recalled by: Manufacturer, by letter dated June 22, 1982. Firm initiated recall
Distribution: California, Colorado, Massachusetts, Illinois, Texas
Size & Quantity: 16,550 connectors were shipped
Reason: Product may separate at the joint between the molded ends and the stainless steel tube, resulting in leakage during use.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Enteric Coated Aspirin Tablets, 5 grains, an OTC analgesic in 1000 tablet bottles, Recall #D-102-2
Code: Lot #2201E1, EXP 5/83
Manufacturer: Standard Pharmacal Corporation, Elgin, Illinois
Recalled by: Manufacturer, by letter, July 16, 1982. Firm initiated recall
Distribution: Florida, Ohio, California, New York
Size & Quantity: Firm estimates none remains on market
Reason: Product contains non-aspirin salicylates in excess of USP limits.

Product: Tridil Nitroglycerin for Injection; 5 mg./ml. in 10 ml. amber glass ampuls, an Rx drug for control of blood pressure in perioperative hypertension associated with surgical procedures, congestive heart failure associated with acute myocardial infarction, and production of controlled hypotension during surgical procedures, Recall #D-104-2
Code: Starter kits lot #'s C1010, C1011, C2019, C2020; maintenance packs lot #'s M1052, C1001, C1002, C1003, C1004, C1006, C1007, C1012, C1013, C2049, C2050
Manufacturer: Arnar-Stone Del Caribe, Inc., Aquadilla, Puerto Rico
Recalled by: American Critical Care, Division of AHSC, McGaw Park, Illinois, by letter, on or about August 4, 1982. Firm initiated recall
Distribution: Nationwide, South Africa, Canada, Lebanon, Australia, UK
Size & Quantity: Firm estimates 42,010 ampuls remain on market
Reason: Possible presence of particulate matter.

Product: Cyclapen-W Oral Suspension, an Rx drug in 100 ml. and 200 ml. glass bottles; 125 mg./5 ml. and 250 mg./5 ml. in each bottle size, Recall #D-105/106-2
Code: All lots
Manufacturer: Wyeth Laboratories, Inc., West Chester, Pennsylvania
Recalled by: Wyeth Laboratories, Inc,, Radnor, Pennsylvania, by sales representatives, July 29, 1982. Firm initiated recall

Distribution: Nationwide
Size & Quantity: Approximately 50,000 bottles of various sizes and strengths were distributed
Reason: Lack of assurance of declared potency after reconstitution.

Product: "Fonseca" and "Del Golfo" brands, precooked, peeled, deveined, vacuum packed, pasteurized, frozen langostinos. Products are imported from El Salvador, packed in 12 ounce packages, 48 packages per master carton. Langostinos are a shrimp-like crustacean ready to eat, Recall #F-250-2
Code: "Fonseca" warehouse lot #15438, "Del Golfo" warehouse lot #20188
Manufacturer: Multipesca, S.A. de C.V., San Salvador, El Salvador
Recalled by: Darik Enterprises Inc., Woodside, New York (importer/distributor), by letters mailed August 2, 1982 for the "Fonseca" brand and August 9, 1982 for the "Del Golfo" brand. Firm initiated recall
Distribution: Northeastern United States
Size & Quantity: 2,000 cartons were distributed
Reason: Bacterial contamination.

Product: B (beta) Neocept, pregnancy test kit, in 50 and 300 test sizes, an in-vitro diagnostic for professional use, Recall #T-150-2
Code: Kit carton numbers 1181135, 2181135, 3281135, 4381135, 5481135, product number 135
Manufacturer: Organon, Inc., West Orange, New Jersey
Recalled by: Manufacturer, by telephone, December 29, 1981 with follow-up mailgrams and visits January 18-19, 1982. Firm initiated recall complete
Distribution: Nationwide
Size & Quantity: Firm estimates none remains on market
Reason: The positive controls gave sporadic false negative results when used according to label instructions.

Product: Yoshida Panoura 8 and 8C, panoramic dental X-ray units in daily use, Recall #R-016-2
Code: Models 8 and 8C
Manufacturer: Yoshida Dental, Japan
Recalled by: Kaycor International, Inc., Evanston, Illinois (importer). FDA approved the firm's corrective action plan on May 14, 1982. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: 63 units were introduced into U.S. commerce

Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968 in that there is a discrepancy in mA accuracy statements; the X-ray beam is larger than the image receptor size; and the technique factors are not visible from operator's position.

Disposition of Prosecutions:

Defendant: Monllor & Boscio Sucesores, Inc., Ponce, Puerto Rico and Enrique Petrovich Boscio, a corporate officer

Nature of Charges: Seven counts of holding food in a warehouse under insanitary conditions

Disposition: The corporation pleaded guilty to six counts and a corporate officer pleaded guilty to one count of violating the adulteration provisions of the statute. The defendants were fined $500 per count for a total of $3500.

Note:

Tomac Wet Dressing Pack with Saline Solution, Recall #T-201-2, a Class II which appeared on the August 11, 1982 Enforcement Report catalog number should read 23240-010.

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August 25, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Ames Glucometer Reflectance Photometer, a small battery-powered instrument designed to provide to the user a numerical "reading" of blood sugar test results obtained with dextrostix reagent strips, Recall #T-203-2
Code:	Model 5580, s/n 55001 through 66999; Model 5581, s/n 30001 through 32999; Model 5595, s/n 5001 through 5599; Model 5599, s/n 5001 through 5999
Manufacturer:	Ames Division, Miles Laboratories, Inc., Elkhart, Indiana
Recalled by:	Manufacturer, by letter, July 2, 1982. Firm initiated recall
Distribution:	Nationwide, Australia, France, Great Britain, South Africa
Size & Quantity:	5,056 units of model 5580; 1,338 units of model 5581; none of model 5595; 750 units of model 5599 were distributed
Reason:	Device may give intermittent erroneous elevated values for glucose due to a modified printed circuit.

HE 20. 4039:

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Isosorbide Dinitrate 5 mg. oral tablets in 100 tablet bottles, an Rx drug used for treatment of angina pectoris, Recall #D-107-2
Code: Lot #45195, EXP 8/84
Manufacturer: West-ward Inc., Eatontown, New Jersey
Recalled by: Manufacturer, by telephone, July 13, 1982 with follow-up letter to United Research Laboratories (URL), Philadelphia, Pennsylvania (own label distributor), August 4, 1982. Firm initiated recall
Distribution: One consignee in Philadelphia, Pennsylvania
Size & Quantity: 4800/100 tablet bottles were shipped
Reason: Labeling mix-up. 100 tablet bottles labeled as isosorbide dinitrate oral 5 mg. tablets (pink colored), control number 45195 were found to contain isosorbide dinitrate oral 10 mg. tablets (white tablets).

Product: Bisacodyl U.S.P. 5 mg. Enteric Coated Tablets, an OTC laxative packaged in bottles of 100 and 1000 tablets and bulk drums, Recall #D-108-2
Code: Lot #'s 032109, EXP date 3-84; 012013, EXP 1-84
Manufacturer: Sidmak Laboratories, Inc., East Hanover, New Jersey
Recalled by: Manufacturer, by letters, July 27, 1982. Firm initiated recall
Distribution: Florida, New Jersey, New York, Connecticut, Iowa, and California
Size & Quantity: Unknown
Reason: Lot #032109 failed USP requirements for potency, content uniformity and disintegration, and Lot #012013, failed USP disintegration test.

Product: Salad dressing packed under a generic label, 32 fluid ounces (1 quart) 946 ml., Recall #F-251-2
Code: Day code 060183
Manufacturer: C.H.B. Foods, Pico-Rivera, California
Recalled by: Manufacturer, by telephone, June 23, 1982. Firm initiated recall
Distribution: California, Arizona, Nevada, Maryland, Virginia, North Carolina, Texas
Size & Quantity: Firm estimates three cases remain on market
Reason: Product was contaminated with Lactobacillus, mold/yeast due to improper/inadequate sanitizing of the filling line.

Product: Codman's Cloward Lumbar Lamina Blade (small and large). The product is part of a retractor set, used to retract lamina in lumbar surgery, Recall #T-205/206-2
Code: Stock #'s S/N 50-1343 (large) and S/N 50-1342 (small)

Manufacturer: Seifried Chirurgische, West Germany
Recalled by: Codman & Shurtleff, Inc., Randolph, Massachusetts, by telephone to domestic accounts and by telex to foreign accounts July 28, 1982. Firm initiated recall.
Distribution: Nationwide and international
Size & Quantity: 231 blades were distributed
Reason: The retaining pin may break away from the retractor blade. The pin, which is part of the blade, fits into a retractor body unit.

Product: (a) Sumtan-I: home tanning equipment; (b) Sumtan-II: home tanning equipment; (c) Eclipse X: commercial tanning equipment; (d) Eclipse XI: commercial tanning equipment; (e) Eclipse XII: dual commercial tanning equipment; (f) Tanarama V: commercial combination tanning-dressing booth, Recall #R-026-2
Code: (a) Stock #108; (b) Stock #109; (c) Stock #115; (d) Stock #114; (e) Stock #113; (f) Stock #124
Manufacturer: Marketing Consultants, Bartlett, Tennessee
Recalled by: Marketing Consultants of America Corporation, Memphis, Tennessee, by letter, November 24, 1981. Firm initiated field correction
Distribution: Tennessee, Kentucky, Mississippi, Georgia, Florida, Missouri, Texas, Michigan, New York, Illinois, Colorado, Louisiana, North Carolina, Pennsylvania, South Dakota, Nebraska, Arkansas, Washington State, Virginia, Oklahoma, Arizona
Size & Quantity: 47 units were sold
Reason: Products lacked required certification and warning labeling.

Seizure Actions Filed:

Product: Nicozol Capsules & Elixir (82-276-721)
Charge: Products are new drugs marketed without approved New Drug Applications or notices of claimed investigational exemption
Firm: The Vale Chemical Company, Inc., Allentown, Pennsylvania
Filed: August 12, 1982 - U.S. District Court for the Western District of Tennessee; Civil #82-2593-W, FDC #63765.

Product: A-Van Capsules (82-276-257)
Charge: Product is a new drug marketed without an Approved New Drug Application or notice of claimed investigational exemption
Firm: D.M. Graham Laboratories, Inc., Hobart, New York
Filed: August 12, 1982 - U.S. District Court for the Western District of Tennessee; Civil #82-2594-W, FDC #63766.

Disposition of Injunctions:

Defendant: Tablicaps, Inc., Franklinville, New Jersey
Nature of Charges: Violating Current Good Manufacturing Practice Regulations
Disposition: Permanent injunction prohibiting all manufacture or shipment of drug products. U.S. District Court for the District of New Jersey; INJ #1005.

Disposition of Prosecutions:

Defendant: Carr Brothers Institutional Foods and Paper Company, Inc., Kenneth R. Carr and James K. Carr, Plant City, Florida
Nature of Charges: Holding food in a warehouse under insanitary conditions.
Disposition: Defendants pleaded guilty to two counts, fines of $1,000 per count for the Corporation, $500 per count for each individual, and six months unsupervised probation for each individual. U.S. District Court for the Middle District of Florida, at Tampa.

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PROSECUTION: A criminal action filed by FDA against a company or individual charging violation of the law. Prosecutions listed below have been filed with a court but not yet tried or concluded.

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

September 1, 1982

- **Recalls and Field Corrections:**

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Statzyme LDH (L-P), an in-vitro diagnostic kit for the quantitative determination of serum lactate dehydrogenase (LDH), Recall #T-204-2
Code: Lot numbers 72C350, 72D516, 72B124, 71P831, 71D688, 71K308, 71C448, 72C336, 72D553, 72B197, 72B133, 71K384, 71N604, 71P838, 71S925, 71C438, 71D573, 71E928, 71H001, 71J139, 71M590, 72D560, 72B250, 71K402, 71N655, 71H949, 71D663, 72B148
Manufacturer: Worthington Diagnostic Systems, Inc., Subsidiary of Flow General, Inc., Freehold, New Jersey
Recalled by: Manufacturer, by telephone, July 6, 1982 and extended by letter, July 28, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: 16,031 kits and 152,327 individual vials were distributed
Reason: Product will lose stability after reconstitution when stored at labeled temperatures.

Product: Mallinckrodt Hemoglobin Test Kit, in-vitro reagents for the quantitative colorimetric determination of hemoglobin in blood, Recall #T-207-2
Code: Lot 811255, EXP 12/3/82, catalog #G507-00
Manufacturer: Mallinckrodt, Inc., Bohemia, New York
Recalled by: Manufacturer, by letter, August 4, 1982. Firm initiated recall
Distribution: Nationwide, Australia, Trinidad, United Arab Emirates
Size & Quantity: Firm estimates 325 kits/100 tests each are in commerce
Reason: Product may yield elevated hemoglobin test results.

HE 20.4039:

Product: Supra "C" 125 capacitor discharge mobile X-ray systems, Recall #R-021-2
Code: Serial numbers: 263A83, 263A44, 263A47, 263A118, 263A88, 263A37, 263A110, 263A41, 263A43, 263A36, 263A33-34, 263A45, 263A48, 263A35*, 263A104, 263A49, 263A105, 263A77, 263A42, 263A136*
*Units are under control of recalling firm
Manufacturer: CGR Medical Corporation, Baltimore, Maryland
Recalled by: Manufacturer. FDA approved the firm's corrective action plan June 25, 1982. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: 19 uncorrected units are subject to field correction
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968. Due to difference in test parameters, the suspect units failed the beam quality section of the standard because an inadequate aluminum filter was placed into the units.

Product: Alpo brand "Liver Chunks Dinner For Dogs," 14-1/2 ounce cans, Recall #V-021-2
Code: 15404/1211, 15404/1213, 15404/12151, 15404/1253
Manufacturer: Allen Products Company, Inc., Allentown, Pennsylvania
Recalled by: Manufacturer, by telephone, July 23, 1982 with follow-up letter. Firm initiated recall
Distribution: New York, West Virginia, Connecticut, South Carolina, Pennsylvania, Tennessee, Ohio, New Jersey, Virginia, Georgia, North Carolina, Maine, Massachusetts, Rhode Island, District of Columbia, Vermont, Florida, New Hampshire, Maryland, Kentucky and military consignees
Size & Quantity: Firm estimates approximately 1200 cases remain on market
Reason: Abnormal cans (swells). Product was found to be decomposed. Both Department of Defense and FDA analysis revealed the presence of Clostridium organisms.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Anthra-Derm (anthralin) Ointment, 1 1/2 ounce tubes, (4 strengths) 1%, 0.5%, 0.25%, 0.1%, an Rx drug for treatment of psoriasis, Recall #D-109/112-2
Code: 37474, 37475, 37503, 37504, 37583, 37634, 37636, 37671, 37707, 37710, 37711, 37763, 37784, 37807, 37841, 37843, 37844, 37880, 37882, 37921, 37923, 37969, 38596, 38598, 38599, 38630, 38631, 38633, 38707, 38716, 38718, 38719, 38746
Manufacturer: Dermik Laboratories, Wm. H. Rorer, Inc., Fort Washington, Pennsylvania
Recalled by: Manufacturer, by internal memo, January 29, 1982. Firm initiated recall complete
Distribution: Nationwide
Size & Quantity: Unknown
Reason: Subpotency. Product does not maintain potency for labeled expiration period.

Product: Hydroxyzine HCl Injection, USP 25 mg./ml., an Rx drug used as a mild tranquilizer, Recall #D-113-2
Code: Lot #M122UK, EXP 9/85, #M078UN, EXP 11/85
Manufacturer: Sterling Drug Inc., McPherson, Kansas
Recalled by: Sterling Drug Inc., New York, New York, by letter, August 16, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 2172 Boxes of 10's were distributed between October, 1981 and July 1982 and approximately 15 percent remains on market
Reason: Mislabeled - Some boxes containing individual units state incorrect strength (100 mg/2 ml.).

Product: HHR Tablets containing hydrochlorothiazide 15 mg., hydralazine HCl 25 mg. and reserpine 0.1 mg., an Rx drug used as an anti-hypertensive agent, Recall #D-114-2
Code: Lot #080676 EXP 11/82, 090742 EXP 6/83
Manufacturer: Bolar Pharmaceutical Company, Inc., Copiague, New York
Recalled by: Manufacturer, by telephone, May 20, 1982. Firm initiated recall complete
Distribution: Nationwide
Size & Quantity: Firm estimates none remains on market
Reason: Product failed USP content uniformity requirement for reserpine.

Product: Petro Syllium No. 1 in 16 ounce bottles, a psyllium emulsion containing mineral oil, an OTC oral laxative for relief of constipation, Recall #D-115-2
Code: Lot #1 J08 EXP 10/85
Manufacturer: Ayerst Laboratories, Division of American Home Products Corporation, Rouses Point, New York

Recalled by: Whitehall Laboratories, Division of American Home Products Corporation, New York, New York, by letter, August 4, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates 7,328 bottles were distributed
Reason: Yeast and mold contamination.

Product: French Style Green Beans 15-1/2 ounce cans under the Pantry Pride, Ideal, Stop and Shop, Town House, Hy-Top, Ann Page, Jewel Pride, National, Staff, Red and White, IGA, Fine Fair, Parade, Goya, Food Town, Foodland, Shop-Rite, Montco, Aunt Nellie, Price Chopper, Market Basket, Purity Supreme, Generic Brand labels, Recall #F-252-2
Code: IFGBN/71990, IFGRN/71990, IFGRN/72070, IFGBN/72070, IFGRN/02630, IFRRN/02630,-FG--/02570, -FG--/02560, -FG--/71980, -FG--/02670, -FR--/02570, -FR--/02560, -FR--/71980, -FR--/02670 with the "-" representing missing letters/numbers of the code which are not pertinent to identifying lots under recall

Manufacturer: C.B. Foods, Division of Curtice Burns Inc., Oakfield and South Dayton, New York

Recalled by: C.B. Foods, Division of Curtice-Burns Inc., Rochester, New York, by telephone, June 7, 1982 with follow-up letters, June 10 and 17, 1982. Firm initiated recall

Distribution: Eastern United States

Size & Quantity: Firm estimates less than 200 cases remain on market

Reason: Abnormal cans including soft swell, springers, flippers due to age of product and product interaction with interior enamel can liners at bead structure.

Seizure Actions Filed:

Product: Frozen Salmon (82-279-888)

Charge: Adulterated - Product consists in part of decomposed salmon

Firm: Queen Fisheries, Dillingham, Alaska

Filed: August 12, 1982 - U.S. District Court for the Western District of Washington at Seattle; Civil #C82-941, FDC #63771.

Product: Drugs, liquid and capsules, containing pentylenetetrazol (82-341-394)

Charge: Products are new drugs marketed without Approved New Drug Applications or notices of claimed investigational exemption; Misbranded - Labeling fails to bear adequate directions for use

Firm: Dunhall Pharmaceuticals, Inc., Gravette, Arkansas

Filed: August 16, 1982 - U.S. District Court for the Western District of Arkansas at Fayetteville, Civil #82-5128, FDC #63782.

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September 15, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product: Heparin Sodium Injection USP in 5 ml. ampuls without preservative, 1000 USP Heparin units/ml., an Rx anticoagulant for IV, IM or SC use, Recall #D-126-2
Code: Lot #81275 EXP 12/84
Manufacturer: Torigian Laboratories, Inc., Queens Village, New York
Recalled by: Manufacturer, by telephone, August 10, 1982 and letters, August 19, 1982 and August 24, 1982 to own label distributor, O'Neal, Jones and Feldman, St. Louis, Missouri. Firm initiated recall
Distribution: Nationwide with possible international distribution
Size & Quantity: 7175/5 ml. ampuls were distributed in November 1981. The firm estimates none remains at the distributor; quantity remaining in sub-distribution is unknown
Reason: Product is non-sterile.

HE 20.4039:

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Model 200 Transport Ventilator, Recall #T-213-2
Code: Serial numbers A200-A299, B200-B299, C213
Manufacturer: Healthdyne, Marietta, Georgia
Recalled by: Manufacturer, by letter, July 15, 1982. Firm initiated recall
Distribution: Nationwide, Australia, Canada, Japan
Size & Quantity: 90 units were distributed
Reason: Two tubing lengths located in the gas input section of the ventilator could rupture when gas input pressure is high and the ambient temperature above 80 degrees F.

Product: Aid Dog Wormer Capsules Worm X for removal of ascarids from dogs, packaged in capsule trays each containing 3, 4, 9, 15, or 20 capsules for dogs of various weights, Recall #V-024-2
Code: 9086, 9087, 9088, 9131, 9144, 9145, 9151, 9158, 9172, 1039, 1043, 1082, 1089
Manufacturer: R.P. Scherer Corporation, Detroit, Michigan
Recalled by: Agribusiness Marketers and Investors, Inc., Baton Rouge, Louisiana (repacker), by letters, December 15, 1981 and June 15, 1982. Firm initiated recall
Distribution: One own-label distributor in Okeechobee, Florida
Size & Quantity: Approximately 263,802 capsules of all types were distributed
Reason: Product was packaged in a blister trade pack which caused significant stability problems.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Hydroxyzine HCl Tablets, 10 mg., 25 mg., 50 mg. packaged in 100, 500 and 1000 tablet bottles, Recall #D-119/121-2
Code: 10 mg. - H02768 EXP 11/82, G03188 EXP 12/82; 25 mg. - F02758 EXP 10/82, F02918 EXP 11/82, F10148 EXP 1/83; 50 mg. - F03248 EXP 1/83, A20678 EXP 5/84
Manufacturer: Lemmon Company (formerly Premo Pharmaceutical Labs), South Hackensack, New Jersey
Recalled by: Manufacturer, by letter, August 17, 1982. Firm initiated recall
Distribution: Nationwide and Canada

Size & Quantity: 8671 bottles of 100's, 6668 bottles of 500's, 2219 bottles of 1000's were distributed
Reason: Product fails dissolution requirements.

Product: Promethazine with Dextromethorphan Expectorant, an Rx oral liquid cough medication packaged in 4 ounce amber glass bottles and 16 ounce and one gallon amber Polyethylene bottles, Recall #D-122-2
Code: Lot #12644 EXP 3/83
Manufacturer: Bay Laboratories, Inc., Skokie, Illinois
Recalled by: Manufacturer, by telephone, August 4, 1982 with follow-up letters mailed August 13 or 16, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates none remains on market
Reason: Product is subpotent in the promethazine ingredient.

Product: Bufalo Mexican Hot Sauce, 5 3/8 ounce bottles, 24 bottles/case, Recall #F-254-2
Code: No codes on bottles or cases
Manufacturer: Empacadora Bufalo, S.A., Mexico, D.F. Mexico
Recalled by: Amigo Quality Foods, Inc., Laredo, Texas (importer), by telephone on or about July 20, 1982. Firm initiated recall
Distribution: Texas, Oklahoma, Illinois
Size & Quantity: 550 cases were shipped
Reason: Insect fragments and hair in product.

Product: Forceps, rubber dam clamp, dental, under the "Miltex" name, used in dental procedures to maneuver rubber dam clamps in a patient's mouth, Recall #T-214-2
Code: None, national stock #6520-00-531-6000
Manufacturer: Gebruder Berchtold Tuttlinger, West Germany
Recalled by: E. Miltenberg, Inc., Lake Success, New York (importer), by telephone and letter dated January 8, 1982. Firm initiated recall complete
Distribution: Three Defense Department depots in Virginia, California, Tennessee
Size & Quantity: Firm estimates none remains on market
Reason: Fractures and cracks along product handle.

Product: Wilson's Goat Ration, 16%, in 50 pound paper bags intended as feed for goats, Recall #V-023-2
Code: No codes
Manufacturer: Wilson's Coal & Grain Company, Lakeville, Indiana

Recalled by: Manufacturer, by visit, July 14, 1982. Firm initiated recall complete
Distribution: Lakeville, Indiana
Size & Quantity: Firm estimates none remains on market
Reason: The firm mixed a medicated calf starter containing neomycin and oxytetracycline into a non-medicated goat feed. The mix-up was discovered by Indiana State Chemists Office during an inspection of the firm.

NOTE:

Anthra-Derm (anthralin) Ointment, 1 1/2 ounce, Recall #D-109/112-2, a Class III which appeared on the September 1, 1982 Enforcement Report has been extended to include lot numbers 37635, 37922, 38717.

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September 22, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

None

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Literature that promotes various "Don M" Aloe Vera products for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man by the Don M. Company, Recall #D-127-2
Code:	Not coded
Manufacturer:	Don M. Company, Tyler, Texas
Recalled by:	Manufacturer, by letters mailed on or about September 3, 1982. Firm initiated recall
Distribution:	Nationwide
Size & Quantity:	Approximately 200,000 copies of literature were distributed
Reason:	Promotional material suggests that the products are effective in treating a variety of disease conditions such as cancer, heart disease, diabetes, and tuberculosis.

HE 20. 4039:

Product: Delta Brand Sardines packed in tomato sauce, 15 ounce cans, Recall #F-255-2
Code: "DESTO/22293"
Manufacturer: Presena SA Mariano De Los Santos, Lima, Peru
Recalled by: Delta Brands International Corporation, Miami, Florida, by telex, April 26, 1982. Firm initiated recall complete
Distribution: One consignee in Honolulu, Hawaii
Size & Quantity: Firm estimates none remains on market
Reason: Excessive histamine levels.

Product: Cold Cure Salmon under the Bagel Mate Sliced Smoked Salmon and Bagel Mate Nova Sides Smoked Salmon Brands, Recall #F-256/257-2
Code: Not coded
Manufacturer: Deli-Delight Food Company, Maryland Heights, Missouri
Recalled by: Manufacturer, by telephone beginning August 27, 1982. Firm initiated recall
Distribution: Chicago, Illinois and Dallas, Texas
Size & Quantity: Firm estimates 675 pounds remain on market
Reason: Excessive sodium nitrite.

Product: Hollywood Health Foods Natural Peanut Butter in 16 ounce jars, Recall #F-275-2
Code: "80262" stamped on carton
Manufacturer: Hain Pure Food Company, Inc., Los Angeles, California
Recalled by: Manufacturer, by visit, August 19, 1982. Firm initiated recall
Distribution: Southern California, Nebraska
Size & Quantity: Firm estimates none remains on market
Reason: Product has been found to be over tolerance for aflatoxin.

Product: X-Cel X-ray Podiatry X-ray units, Model P-75M (mobile), and Model P-75W (wall), Recall #R-022-2
Code: Model P-75M and Model P-75W
Manufacturer: X-Cel X-Ray Corporation, Crystal Lake, Illinois
Recalled by: Manufacturer, by letter, February 12, 1982. Firm initiated field correction
Distribution: Pennsylvania, New York, California, Minnesota, Ohio, New Mexico, Virginia, Florida, North Carolina
Size & Quantity: Approximately 16 units were produced
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968 because the systems were not provided with means to limit the source-to-skin distance to not less than 30 centimeters; markings on removable apertures were not always legible. Beam limiting device labels listed only one of two possible SIDs.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Paregoric, USP, Anhydrous Morphine 5 ml., unit dose cups, packaged 10 cups/tray, 10 trays/shipping case, one product insert/case, Recall #D-123-2
Code: Lot numbers 810667, 821341, 810738, 810767, 810764
Manufacturer: Roxane Laboratories, Columbus, Ohio
Recalled by: Manufacturer, by freezing stock at two warehouses under their control, and replacing misprinted inserts with revised and corrected inserts, April 8, 1982. Firm initiated field correction complete
Distribution: Nationwide
Size & Quantity: Firm estimates 974 cases were used and/or placed in commerce
Reason: Product insert was misprinted to declare 12 mg. per 5 ml. of product. There is actually 2 mg. per 5 ml. of product. Individual unit dose cups are labeled correctly.

Product: Flint Synthroid (Levothyroxine Sodium USP) for Injection, 100 mcg.; lyophilized product in 10 ml. vials, 6 vials per carton, an Rx drug for replacement therapy for reduced or absent thyroid function, Recall #D-124-2
Code: Catalog code 3P1322, lot #'s 0S011L2, 9S011L7, 9S011N2, 5S011N4, 0S011N6, 6S011N8, 6S011P3, 9S011P6, 7S011R2, 8S011R6
Manufacturer: Travenol Laboratories, Inc., Flint Laboratories Division, Cleveland, Mississippi
Recalled by: Travenol Laboratories, Inc., Flint Laboratories Division, Deerfield, Illinois, by letter, August 30, 1982. Firm initiated recall
Distribution: Nationwide, Puerto Rico, Venezuela
Size & Quantity: Firm estimates 2133 vials remain on market
Reason: Loss of product potency prior to its expiration date.

Product: Par-Tapp Extended Action Tablets, a combination of brompheniramine maleate 12 mg., phenylephedrine HCl 15 mg., and phenylpropanolamine HCl 15 mg., an Rx drug used as an antihistaminic, Recall #D-125-2
Code: Lot numbers 820903 EXP 3/84, 820982 EXP 4/85, 820822 EXP 3/84. Lot #820909 is listed on withdrawal letter but is not a manufactured lot
Manufacturer: Par Pharmaceutical Inc., Upper Saddle River, New Jersey
Recalled by: Manufacturer, by letter, July 30, 1982. Firm initiated recall
Distribution: District of Columbia, New Jersey, Pennsylvania, New York, Georgia, Michigan, Kentucky, Florida, Maryland, California, Ohio, Tennessee, Rhode Island, Texas, Mississippi, Missouri
Size & Quantity: Firm estimates 3,769,600 tablets remain on market
Reason: Mottled tablets due to moisture migrating to the surface after coating.

Product: Stretcher; Models 920, 921, 930, 931, 933, 935, 960, 962, 965, for acute care, general emergency, and surgical purposes, Recall #T-215-2
Code: Serial numbers fall within the range 52175 - 52481 noninclusively. Only 31 units assembled from July 1, 1982 through July 28, 1982 are involved
Manufacturer: Stryker Corporation, Kalamazoo, Michigan
Recalled by: Manufacturer sent packets of information and equipment to representatives for each recalled unit, July 30, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 31 stretchers were distributed during July 1982
Reason: Some stretchers may not have been assembled properly, resulting in the jack controls not functioning properly.

Product: Fractions II and III Paste, for further manufacturing for in-vitro diagnostic use, Recall #B-023-2
Code: Lot #5D16
Manufacturer: New York Blood Center Inc., Blood Derivatives Program, Melville, New York
Recalled by: Manufacturer, by telegram, August 3, 1982. Firm initiated recall
Distribution: One consignee in Miami, Florida
Size & Quantity: Approximately 238.0 kg. was distributed
Reason: Product is labeled as prepared from plasma nonreactive for hepatitis B surface antigen (HBsAg); however, one unit of plasma reactive for HBsAg was utilized in manufacture.

Product: Recovered Human Plasma (for manufacturing use only), Recall #B-024-2
Code: F-55386, F-55387, F-55388, F-55389, F-55390, F-55391, F-55392, F-55437, F-55438, F-55439, F-55440, F-55441, F-55442, F-55443, F-55444, F-55445, F-55446, F-55447, F-55448, F-55449, F-55450
Manufacturer: Tri-Counties Blood Bank, Inc., Santa Barbara, California
Recalled by: Manufacturer, by letter dated July 29, 1982. Firm initiated recall
Distribution: One broker in Monrovia, California
Size & Quantity: 21 units were shipped
Reason: Units were labeled as nonreactive for hepatitis B surface antigen (HBsAg) when, in fact, the units had not been tested for HBsAg.

Product: Immune Serum Globulin Powder (Fraction II) and Human Plasma Powder (Fraction II) used for further processing into in-vitro diagnostics, Recall #B-025-2
Code: Lots 2675, 2678, 2679, 2683
Manufacturer: Protein Processors, Inc., Miami, Florida

Recalled by: North American Biologicals, Inc., Miami, Florida (distributor), by telex, August 2, 1982 with follow-up letter, August 9, 1982. Firm initiated recall

Distribution: Canada and Japan

Size & Quantity: 506.72 kilograms were distributed

Reason: Product is labeled as having been prepared from plasma nonreactive for hepatitis B surface antigen (HBsAg); however, one unit of plasma reactive for HBsAg was utilized in manufacture.

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FDA Enforcement Report

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The **FDA Enforcement Report** is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

PROSECUTION: A criminal action filed by FDA against a company or individual charging violation of the law. Prosecutions listed below have been filed with a court but not yet tried or concluded.

SEIZURE: An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods until the matter is resolved. The date listed is the date a seizure request is filed, not the date of seizure.

INJUNCTION: A civil action filed by FDA against an individual or company seeking, in most cases, to stop a company from continuing to manufacture or distribute products that are in violation of the law. Injunctions listed have been filed with the court but not concluded.

RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

September 29, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

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Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Theo-dur 100 mg. sustained action tablet, Theophylline (anhydrous), an Rx drug in unit dose packaging, used for symptomatic relief of asthma and reversible bronchospasm associated with chronic bronchitis and emphysema, Recall #D-129-2
Code:	OY0011 EXP 1/83
Manufacturer:	Key Pharmaceuticals Inc., Miami, Florida
Recalled by:	Manufacturer, by letter, September 2, 1982. Firm initiated recall
Distribution:	Nationwide
Size & Quantity:	Firm estimates 400/100 tablet cartons remain on market
Reason:	A foreign tablet (phenobarbital 100 mg.) was found in a unit dose strip pack.

HE 20.4039:

Product: CS-615 Supplemental Modification Kit used for correcting CS-615 Monitors involved in Recall #T-180-2; Recall #T-219-2
Code: 800 serial numbers between 1957 and 2931 (only 631 units were shipped)
Manufacturer: The Burdick Corporation, Milton, Wisconsin
Recalled by: Manufacturer, by letter dated August 20, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: 631 units were shipped
Reason: The battery may drain quickly due to a wiring problem in the device resulting in a dead battery.

Product: T-E Bloat Protector, Medicated Feed with active ingredient Poloxalene, packed 40/1.25 pound bricks per 50 pound carton and in 50 pound blocks, Recall #V-025-2
Code: All lots
Manufacturer: T-E Agri Supply Company in Clovis, New Mexico and Oklahoma City, Oklahoma
Recalled by: T-E Agri Supply Company, Amarillo, Texas, by telephone, August 23, 1982. Firm initiated recall complete
Distribution: New Mexico, Oklahoma, Texas
Size & Quantity: Firm estimates none remains on market
Reason: Product was manufactured and distributed without an approved New Animal Drug Application.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Ergonovine Maleate Tablets, USP, 0.2 mg, in bottles of 1000's, an Rx drug indicated for the prevention and treatment of post partum and post abortal hemorrhage due to uterine atony, Recall #D-128-2
Code: Lot number 1E110
Manufacturer: The Vitarine Company, Inc., Springfield Gardens, New York
Recalled by: Manufacturer, by telephone, September 7, 1982 with follow-up letters, September 8, 1982. Firm initiated recall
Distribution: New York, Illinois, New Jersey, Michigan, Florida, Texas, California, Ohio
Size & Quantity: 442 bottles of 1000 tablets each were shipped
Reason: Product failed USP content uniformity requirements.

Product: Phenobarbital 30 mg Tablets, an Rx drug administered orally as an anti-convulsant, hypnotic or sedative, packed in white plastic bottles of 100, Recall #D-130-2
Code: Lot #35961

Manufacturer: Richlyn Laboratories, Inc., Philadelphia, Pennsylvania
Recalled by: Consolidated Midland Corporation, Brewster, New York, by telephone and follow-up letter, September 2, 1982. Firm initiated recall
Distribution: One consignee in Eldridge, California
Size & Quantity: Firm estimates 670/100 tablet bottles remain on market
Reason: One 100 tablet bottle of 30 mg. phenobarbital was found to contain an odd size tablet that was determined to be a 15 mg phenobarbital tablet.

Product: Various Flavors of Fruit Beverage Base Drinks in one gallon containers packed under "Orogold," "Florida Julep," "JUS-MADE," and "JUS-MADE JULEP" labels: Apple, Cherry-Apple, Circus-Lemon, Lemon-Lime, Pineapple-Grapefruit, Pineapple-Orange, Punch, Tangerino, Grape, Orange, Strawberry, Peach, Pink Lemon, Peaches N Cream, Pina Colada, Strawberry N Cream, Pineapple-Coconut flavors, Recall #F-258/274-2
Code: All lots
Manufacturer: Jus-Made, Inc., Dallas, Texas
Recalled by: Manufacturer, by telephone on or about August 27, 1982 with follow-up letters on or about September 6, 1982. Firm initiated recall
Distribution: Available information indicates distribution to Georgia, Florida, North Carolina, Oklahoma, Virginia, Texas, Washington State
Size & Quantity: Not available
Reason: Products contain undeclared saccharin.

Product: (a) Coagachek Fibrinogen Reference (Human), a component of the Coagachek Fibrinogen Test Kit used for the quantitative determination of fibrinogen in plasma, 1 ml. bottle per test kit; (b) Coagachek Thromboplastin, Dried (rabbit brain), for plasma prothrombin time determinations, 10/10 ml. bottles/box; (c) Q-Pak Chemistry Control Serum II (unassayed), a control serum containing constituents generally in the abnormal range used to assess the precision of quantitative laboratory procedures, 20/10 ml bottles/box, Recall #T-216/218-2
Code: (a) List #035-022, component lot #3405B004A EXP OCT 84, kit lot #3414F001AA EXP OCT 83, #3414F002AA EXP SEPT 83, #3414F003AA EXP OCT 83, #3414F004AA EXP JAN 84; (b) List #035-510, bottle lot #0770B007A, box lot #0770B007AA EXP JULY 84; (c) List #045-710, bottle lot #3465B004A, box lot #3465B004AA EXP OCT 84
Manufacturer: Hyland Diagnostics, Division of Travenol Laboratories, Inc., Round Lake, Illinois
Recalled by: Hyland Diagnostics, Division of Travenol Laboratories, Inc., Deerfield, Illinois, by visit, August 18, 1982. Firm initiated recall
Distribution: (a) Nationwide, Australia, Belgium, Brazil, Columbia, Japan, Peru, Puerto Rico, Singapore, South Africa; (b) Colorado, New Mexico; (c) Nationwide

Size & Quantity: Firm estimates (a) 704 kits, (b) None, (c) 900 boxes remain on market
Reason: Some units of these devices may have been assembled in such a way that the stopper may bulge, allowing air and moisture to enter the bottles causing the product to give decreased values for some constituents.

Product: Cilco DKS Wide Angle Cutter, Model 127, a sterile disposable vitrectomy hand-held instrument used in Ophthalmic Vitrectomy procedures, Recall #T-220-2
Code: Lot #03044-4
Manufacturer: Cilco, Inc., Pomona, California
Recalled by: Cilco, Inc., Huntington, West Virginia, by telephone, July 23, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 26 units were distributed
Reason: The device is mislabeled. The Model 125 Vitrophage full-function handpiece cutter is packaged and labeled as Model 127 wide angle cutter.

Product: Hi-Vite Drops, Liquid Multivitamin Supplement in one fluid ounce glass bottle for oral veterinary use in dogs and cats and offspring, Recall #V-022-2
Code: Lot #3963
Manufacturer: Evsco Pharmaceutical Corporation, Buena, New Jersey
Recalled by: Manufacturer, by telephone, July 12, 1982. Firm initiated recall
Distribution: Nationwide and one international consignee
Size & Quantity: Firm estimates 294 one ounce bottles were on the market as of July 12, 1982.
Reason: Product adulterated with a gas forming bacteria.

Seizure Actions Filed:

Product: Baby and Dry Lima Beans (82-299-873)
Charge: Adulterated - Product consists in part of a filthy substance
Firm: Kansas City Terminal Warehouse Company, Kansas City, Kansas
Filed: August 24, 1982 - U.S. District Court for the District of Kansas at Kansas City; Civil #82-2296, FDC #63792.

Product: Drugs containing phentylentetrazol (82-341-488)
Charge: Products are new drugs marketed without approved New Drug Applications or notices of claimed investigational exemption
Firm: Artex Laboratories, Inc., Mayflower, Arkansas
Filed: August 30, 1982 - U.S. District Court for the Eastern District of Arkansas at Little Rock; Civil #LR-C-82-629, FDC #63794.

Product: Blankets in cannisters for use on burn victims (82-221-702)
Charge: Adulterated - Antimicrobial fluid leaked from containers; Misbranded - Label states blanket was packed aseptically and is sterile when it is not
Firm: Trilling Resources Ltd., Woonsocket, Rhode Island
Filed: September 2, 1982 - U.S. District Court for the Western District of Louisiana at Lafayette; Civil #82-2180 SEC. S, FDC #63791.

Civil Penalty Filed:

Against: Goldentone Suntanning Systems, Inc., Shelbyville, Tennessee and Gary G. Throneberry, President
Product: Suntanning Booths, Misc. #669
Charge: Manufacturing (assembling at the site of use) and selling tanning booths that failed to comply with the performance standard for sunlamp products; failing to notify the purchaser, and by failing to repair, replace, or make a refund of the cost for each tanning booth that failed to comply with the performance standard; failing to allow access to and copying of distribution records for tanning booths; certifying that tanning booths complied with the performance standard when in the exercise of due care they would have had reason to know that such certification was false and misleading in a material respect.
Filed: June 23, 1982 - U.S. District Court for the Eastern District of Tennessee, Winchester Division; Civil #CIV-4-82-28.

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October 6, 1982

Recalls and Field Corrections:

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NONE

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Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	(a) Walgreen's Nature's Finest Aloe Vera 75% Moisturizing Lotion with Lecithin in 8 ounce plastic bottles; (b) Walgreen's Nature's Finest Aloe Vera 75% Moisturizing Cream with Lecithin in 4 ounce plastic jars, Recall #F-276/277-2
Code:	Lot numbers (a) BWC-2, BWD-2; (b) BSI-2
Manufacturer:	Walgreen Laboratories, Inc., Chicago, Illinois
Recalled by:	Walgreen Company, Deerfield, Illinois, by telephone and follow-up letter, September 3, 1982. Firm initiated recall
Distribution:	Nationwide and Puerto Rico
Size & Quantity:	Firm estimates 14,811 bottles of lotion and 19,545 jars of cream remain on market
Reason:	Contamination with bacteria, including Pseudomonas aeruginosa.

HE 20.4039:

Product: "Autostik TM Arterial Blood Gas Kit For pH and Blood Gas Analysis for in-vitro diagnostic use (For Arterial Puncture) For Single Patient Use...Autostik 2-1/2cc...syringe with vented plunger contains approximately 100 units of lyophilized lithium heparin...contents of individual packages are sterile provided packages are neither opened nor damaged before use. Caution: Federal (USA) law restricts this device..." packaged 100 units/case, Recall #T-221-2

Code: Glass model catalog numbers G-2522, G2523, G2622, G-2022, G-2023; lot numbers 18A, 29A, 30A, 53A, 59A, 60A, 62A, 63A, 64A, 67A, 73A, 95A, 96A, 107A, 118A. These lot numbers are all six digits with enough zeros being added in front to equal six digits

Manufacturer: Marquest Medical Products, Inc., Englewood, Colorado

Recalled by: Manufacturer, by mailgram, August 6, 1982 with follow-up letter, September 1, 1982. Firm initiated recall

Distribution: Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Kansas, Massachusetts, Michigan, Minnesota, Missouri, Montana, North Carolina, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Virginia, Washington State, Wisconsin, West Virginia

Size & Quantity: Firm estimates 120 remain at wholesale level

Reason: A component used in the O-ring contributes to possible leaking.

Product: "Aspirator TM for pH and Blood Gas Analysis for in-vitro diagnostic use. 1 cc plastic syringes...Contains approximately 30 units of lithium heparin as an anticoagulant...intended for use as an anticoagulant in the syringe only...contents of package are sterile provided package is neither opened nor damaged before use. Caution: Federal (USA) law restricts this device...use once only - not for injection..." Packaged 100 individual syringes/case, Recall #T-222-2

Code: Product code MQ601, lot numbers 002156, 002244, 002263

Manufacturer: Marquest Medical Products, Inc., Englewood, Colorado

Recalled by: Manufacturer, by mailgrams, August 6, 1982 with follow-up letter dated September 1, 1982. Firm initiated recall

Distribution: Alabama, Arkansas, California, Colorado, Florida, Georgia, Indiana, Massachusetts, North Carolina, Pennsylvania, Tennessee, Texas

Size & Quantity: Firm estimates 100 cases remain on market

Reason: Packaging defects in the plastic bag may compromise the labeled sterility.

Product: "Aspirator TM for pH and Blood Gas Analysis for in-vitro diagnostic use. 1 cc plastic syringe...Contains approximately 30 units of lithium heparin as an anticoagulant...intended for use as an anticoagulant in the syringe only...Contents of package are sterile provided package is neither opened nor damaged before use. Caution: Federal (USA) law restricts this device...use once only - not for injection...", packaged 100 individual syringes/case, Recall #T-223-2
Code: Product code MQ601, lot numbers 000563, 002088, 002093, 002094, 002107, 002111, 002120, 002123, 002144, 002154, 002156, 002159, 002186, produced between April 26 and June 18, 1982
Manufacturer: Marquest Medical Products, Inc., Englewood, Colorado
Recalled by: Manufacturer, by mailgrams, August 6, 1982, with follow-up letter, September 1, 1982. Firm initiated recall
Distribution: Alabama, Arizona, California, Colorado, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Louisiana, Massachusetts, Michigan, Minnesota, Missouri, Montana, North Carolina, New York, Ohio, Oregon, Pennsylvania, Tennessee, Texas, Virginia, Washington State
Size & Quantity: Firm estimates 238 cases of 100 units each remain at the wholesale level
Reason: The heparin pellets may have recrystallized on the inside of the syringes.

Product: PBL Collimation System including a collimator, a bucky tray, an electronic logic, and various connecting cables and sensing devices, Recall #R-024-2
Code: Collimator model G0865, G5139; Discrete size sensing bucky tray model G0821; Logic model G5086
Manufacturer: Siemens Corporation, Iselin, New Jersey
Recalled by: Manufacturer. FDA approved firm's corrective action plan, September 2, 1982. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: Firm estimates 1300 systems subject to field correction
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act.

Product: Laser Tire Analyzers, Recall #R-027-2
Code: Model #K160
Manufacturer: Industrial Holographics, Inc. (IHI), Auburn Heights, Michigan
Recalled by: Manufacturer. FDA approved firm's corrective action plan September 13, 1982. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: 25 units subject to field correction

Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968 because the firm produced and shipped products which had noninterlocked operator/maintenance covers over the laser head protective housing. The covers should be interlocked or made to prevent access.

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Product: Tymtran Injection, brand of ceruletide diethylamine 40 mcg/2 ml. as ceruletide, 2 cc amp. in-vivo diagnostic aid, Recall #D-131-2
Code: All D-711, D-711S, D-713 and D-713S
Manufacturer: Farmitalia Carlo ERBA, S.p.A., Milan, Italy
Recalled by: Adria Laboratories, Inc., Dublin, Ohio, by letter mailed September 19, 1982. Firm initiated recall
Distribution: Nationwide and Canada
Size & Quantity: 16,090 ampuls remain on market
Reason: Subpotent.

Product: "Selectogen," Reagent Red Blood Cells, an in-vitro diagnostic test kit; a qualitative test for the detection of unexpected blood group antibodies, Recall #B-026-2
Code: Lot numbers "S698 EXP 16 SEP 82", "S699 EXP 16 SEP 82"; Ortho catalog number 719610
Manufacturer: Ortho Diagnostic Systems Inc., Raritan, New Jersey
Recalled by: Manufacturer, by letter, telex and telephone, August 27, 1982. Firm initiated recall
Distribution: Nationwide, Puerto Rico, Bermuda, Sweden, Australia
Size & Quantity: 1080 kits were distributed
Reason: Hemolysis; mold contamination suspected by firm.

Seizure Actions Filed:

Product: Senilex Tablets (82-256-973)
Charge: Product is a new drug marketed without an Approved New Drug Application or notice of claimed investigational exemption
Firm: O'Neal, Jones & Feldman, St. Louis, Missouri
Filed: August 18, 1982 - U.S. District Court for the Eastern District of Missouri, Eastern Division at St. Louis; Civil #82-1327-C(B), FDC #63784.

Product: M.A.C. Veterinary Counterirritant and Absorbent (82-256-560)
Charge: Product is a new animal drug marketed without an approved New Animal Drug Application or notice of claimed investigational exemption
Firm: Carter-Luff Chemical Company, Inc., Gloversville, New York
Filed: August 30, 1982 - U.S. District Court for the Northern District of New York at Albany; Civil #82-CV-909, FDC #63735.

Product: Rice (82-347-246)
Charge: Adulterated - Product contains live insects and insect larvae and was held under insanitary conditions
Firm: Mr. Special Supermarkets, Inc., Mayaguez, Puerto Rico
Filed: September 1, 1982 - U.S. District Court for the District of Puerto Rico at San Juan; Civil #82-2130, FDC #63790.

Product: Butter (82-403-801)
Charge: Adulterated - Food labeled "butter" contains less than 80% by weight of milk fat, the percentage of milk fat required for butter. The ingredient which has been substituted for the missing milk fat is water
Firm: Beatrice Foods Company, Columbus, Ohio
Filed: September 21, 1982 - U.S. District Court for the Eastern District of Michigan at Detroit, Civil #82-73539, FDC #63831.

Product: Starch Blocker Tablets (82-249-222)
Charge: Product is a new drug marketed without an Approved New Drug Application or notice of claimed investigational exemption
Firm: Sunrise Chemical, Deer Park, Illinois
Filed: September 24, 1982 - U.S. District Court for the Southern District of Illinois; Civil #82-4280, FDC #63793.

Product: AMX Tablets (starch-ex protein concentrate)(82-294-164)
Charge: Product is a new drug marketed without an Approved New Drug Application or notice of claimed investigational exemption
Firm: O'Connor Products Company, Redford, Michigan
Filed: September 29, 1982 - U.S. District Court for the Eastern District of Michigan at Detroit; Civil #82-73661, FDC #63834.

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October 13, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Chunk Light Tuna in Water, brand name "Great Sun Chunk Light Tuna in Water" packed in 6 1/2 ounce cans, Recall #F-001-3
Code: Bottom line codes: 2416, 2424, 2425, 2426, 2428, 2429, 2430, 2501, 2506, 2507, 2509
Manufacturer: Premier Industrial & Development Corporation, Mandaue City, Cebu, Philippines
Recalled by: G.I.C. America, Inc., San Francisco, California (importer/distributor), by telephone, June 28, 1982. Firm initiated recall.
Distribution: Utah
Size & Quantity: 6,000 cases each containing 48 cans were distributed
Reason: Swollen and leaking cans.

HE 20. 4039:

Product:	Anti-K (Anti-Kell) Blood Grouping Serum, for indirect antiglobulin test, Recall #B-001-3
Code:	Lot #K-36 EXP 9/13/82
Manufacturer:	Spectra Biologicals, Division of Becton Dickinson and Company, Oxnard, California
Recalled by:	Becton Dickinson Immunodiagnostics (BDI), Orangeburg, New York, by letter, September 2, 1982. Firm initiated recall
Distribution:	Nationwide, England, Sweden, Spain, Italy, Saudi Arabia, China
Size & Quantity:	Firm estimates none remains on market
Reason:	Vials of Anti-K (Kell), Lot K-36, were mistakenly labeled as Anti-k (Cellano).

Product:	SMR Maxi Chair, an AC powered patient examination chair, Recall #T-224-2
Code:	Model numbers 10000 and 10100
Manufacturer:	Storz Instrument Company, St. Louis, Missouri
Recalled by:	Manufacturer, by letter, September 3, 1982. Firm initiated field correction
Distribution:	Nationwide
Size & Quantity:	Approximately 105 chairs are subject to field correction
Reason:	The chair may drop from the elevated position due to failure of the limit switch in the lift motor.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product:	Orange Enteric Coated Aspirin, 5 grain, an OTC oral analgesic, 100 tablet and 1000 tablet bottles, Recall #D-001-3
Code:	2431, 2482, 2501, 2503, 2504, 2507, 2545, 2584, 2594, 2733, 2734, 2806, 2807, 2808, 2843, 2920, 2921, 2922, 2923, D228, D270, D292, D439, D440, D443, D444, D465, D532
Manufacturer:	Standard Pharmacal Corporation, Elgin, Illinois
Recalled by:	Manufacturer, by telephone with follow-up letters, September 14, 1982. Firm initiated recall
Distribution:	Nationwide
Size & Quantity:	26,130,800 tablets were distributed
Reason:	Inadequate stability data to support the labeled expiration dates.

Product:	Propantheline Bromide Tablets, 15 mg., Recall #D-002-3
Code:	Lot 34727, 25920
Manufacturer:	Richlyn Laboratories, Philadelphia, Pennsylvania
Recalled by:	Manufacturer, by letter dated September 22, 1982. Firm initiated recall
Distribution:	Nationwide

Size & Quantity: Firm estimates 400,000 tablets remain on market
Reason: Product failed USP requirements for xanthanoic acid and was subpotent for propantheline bromide.

Product: Difco Bacto Streptolysin O Reagent, product #0482-60-4, a dehydrated powder to be reconstituted for in-vitro diagnostic use, packaged in 10 ml. vials, 6 vials/package, Recall #T-212-2
Code: Lot numbers 688516 and 701421
Manufacturer: Difco Laboratories Inc., Detroit, Michigan
Recalled by: Manufacturer, by letter dated July 23, 1982 requesting all stock on hand be returned. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates 400 packages of 6 vials remain on market
Reason: Reagent becomes cloudy when rehydrated and yields excessively high titers.

Product: Federation 20% Chicken Starter A+B Medicated, Animal Feed for Chickens, Recall #V-001-3
Code: Not coded
Manufacturer: Federation of Livestock Associations of P.R. Inc., Bo Malecon, Mayaguez, Puerto Rico
Recalled by: Manufacturer, by visit, August 17, 1982. Firm initiated recall
Distribution: Puerto Rico
Size & Quantity: 60 bags/60 pounds each were distributed
Reason: Product's label failed to bear one of the active drug ingredients, ethopabate.

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FDA Enforcement Report

Press Office
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October 20, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Du Chef Pink Peppercorns in Brine, 1 ounce glass jars, 24 jars/master carton, Recall #F-003-3
Code:	Not coded
Manufacturer:	Denis Freres, Paris, France
Recalled by:	Du Chef Fancy Foods, Inc., New York, New York, by letter September 21, 1982. Firm initiated recall.
Distribution:	New York and California
Size & Quantity:	578 cartons of 24/1 ounce jars were distributed
Reason:	Product is not an approved food additive nor is it generally recognized as safe (GRAS).

Product:	Pink Peppercorn in Brine; Pink Peppercorn in Vinegar, drained weights 1.4, 2.8, 10.5 ounces, Recall #F-004/005-3
Code:	Not coded
Manufacturer:	STF International de Transaction, Paris, France

HE 20.4039:

Recalled by: Liberty Ramsey Imports, Carlstadt, New Jersey (importer),by visits beginning February 1982. Firm initiated recall complete
Distribution: Nationwide
Size & Quantity: Firm estimates none remain on market
Reason: Product is not an approved food additive nor is it generally recognized as safe (GRAS).

Product: Toshiba model KCD-10M=6C-B capacitor discharge mobile X-ray units, Recall #R-023-2
Code: Model KCD-10M-6C=B, manufactured during the period of August 1979 through March 1982
Manufacturer: Toshiba of Japan, Tokyo, Japan
Recalled by: Toshiba Medical Systems, Carson, California (importer). FDA approved the firm's corrective action plan by letter, August 2, 1982. Firm initiated field correction
Distribution: Unknown
Size & Quantity: 67 units subject to field correction
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968 in that this model failed to comply with the light localizer illuminance requirement.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Benzopirin Gotas/Antipyrine and Benzocaine Solution, otic drops, analgesic to relieve acute otitus pain, Recall #D-004-3
Code: Lot #FS 3967 EXP 6/84
Manufacturer: Dorasol Labs., Inc., Hato Rey, Puerto Rico
Recalled by: Manufacturer, by letter and visit beginning September 27, 1982. Firm initiated recall
Distribution: Puerto Rico
Size & Quantity: 3,966 one half ounce bottles were distributed
Reason: Subpotency.

Product: Happy-Vale Peaches, canned, irregular slices, yellow cling in light syrup, 29 ounce cans, 24 cans/case, Recall #F-006-3
Code: All product involved appears to be 1980 pack from the Gridley, California plant with EE in the third and fourth positions of the top line
Manufacturer: Libby, McNeil & Libby, Inc., Gridley, California
Recalled by: Borman's Inc., Detroit, Michigan (wholesale distributor), by store bulletin, July 16, 1982. Firm initiated recall complete

Distribution: Michigan, Ohio
Size & Quantity: Firm estimates none remains on market
Reason: Swollen cans.

Seizure Actions Filed:

Product: Peanuts (82-339-017)
Charge: Adulterated - Products have been held under insanitary conditions whereby they may have become contaminated with filth
Firm: Nansemond Cold Storage Company, Suffolk, Virginia
Filed: June 7, 1982 - U.S. District Court for the District of Virginia at Norfolk; Civil #82-434-N, FDC #63724.

Product: Frozen Swordfish (82-252-656)
Charge: Adulterated - Product contains mercury
Firm: Nordic Fisheries, Pittsburgh, Pennsylvania
Filed: October 6, 1982 - U.S. District Court for the Western District of New York at Buffalo; Civil #82-922, FDC #63848.

Product: Frozen Swordfish (82-252-658)
Charge: Adulterated - Product contains mercury
Firm: P.J. Markos Seafood Company, Inc., Ipswich, Massachusetts
Filed: October 6, 1982 - U.S. District Court for the Western District of New York at Buffalo; Civil #82-921, FDC #63849.

Product: Frozen Swordfish (82-252-655)
Charge: Adulterated - Product contains mercury
Firm: Seafood Marketing, Inc., Boston, Massachusetts
Filed: October 6, 1982 - U.S. District Court for the Western District of New York at Buffalo; Civil #82-923, FDC #63850.

Product: Frozen Swordfish (82-350-812)
Charge: Adulterated - Product contains mercury
Firm: Triple M Seafood and Equipment Distributors, Inc., Pompano Beach, Florida
Filed: October 6, 1982 - U.S. District Court for the Western District of New York at Buffalo; Civil #82-924, FDC #63851.

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October 27, 1982

Recalls and Field Corrections:

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NONE

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Product:	Eagle Eye Eye Drops, packaged in 1/2 fluid ounce transparent plastic squeeze bottles with a drop dispenser tip, an OTC herbal eye wash, Recall #D-003-3
Code:	All lots
Manufacturer:	Sand. Oh. Sha., Blackhawk, Colorado
Recalled by:	Manufacturer, by telephone on or about August 20, 1982 with follow-up letter on or about October 1, 1982. Firm initiated recall
Distribution:	California, Colorado, Florida, Oregon, Missouri, Idaho, Arizona
Size & Quantity:	Approximately 750 one-half ounce bottles were produced
Reason:	The product is an unapproved new drug and does not meet specifications of 21 CFR 200.50.

HE 20. 4039:

Product: Imferon (iron dextran for injection USP) 2 ml. ampuls (50 mg. elemental iron per ml.) with 10 ampuls/package, Recall #D-005-3
Code: Lot 3511ML
Manufacturer: Fison Limited Pharmaceutical Division, Loughborough, England
Recalled by: Merrell-Dow Pharmaceuticals, Inc., Cincinnati, Ohio, by mailgrams, September 3, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 3,300 packages of 10 ampuls each remain on market
Reason: An increased frequency of adverse reactions.

Product: Proferdex TM (iron dextran injection) 5 ml. ampule, an Rx injectable iron supplement used for the treatment of iron deficiencies, Recall #D-006-3
Code: JS8KI
Manufacturer: Fisons PIC, Loughborough, England
Recalled by: Fisons Corporation, Bedford, Massachusetts, by letter, September 9, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 585 5/5 ml. packages were distributed. Firm estimates less than 50 percent remains on market
Reason: An increased frequency of adverse reactions.

Product: "Luciferin-Luciferase (purified firefly extract) for in-vitro diagnostic use 5.5 ml.," portion of a bacteriuria screening test kit, to be used in conjunction with firm's Model 101 Clinical Photometer, Recall #T-002-3
Code: Lot #006 EXP 3/83, Diagnostic Science catalog #05-01-02, American Science Products catalog #B 1018-10
Manufacturer: Bio-Chemical Diagnostics, Inc., Farmingdale, New York
Recalled by: Diagnostic Sciences, Inc., San Diego, California, by telephone, September 9, 1982 with follow-up letter dated September 15, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates 136 units remain on market
Reason: The reagent yields incorrect test results due to low potency.

Product: Source Plasma (Human) for manufacturing use only, Recall #B-002-3
Code: Unit bleed #J20878, collection date April 24, 1981
Manufacturer: Gotham Blood Products, Inc., New York, New York
Recalled by: Superior Labs., Ltd., New York, New York, by telephone, September 16, 1982. Firm initiated recall
Distribution: Pennsylvania
Size & Quantity: One unit (651 mls.) subject to recall
Reason: Product is labeled nonreactive for hepatitis B surface antigen (HBsAg); however, it was never tested for HBsAg.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Watkins Supercold Cough Medicine with D-Methorphan Antitussive in 6 fluid ounce glass bottles, Recall #D-007-3
Code: 42730, 42731, 42732, 42733
Manufacturer: Watkins, Inc., Winona, Minnesota
Recalled by: Manufacturer, by letter, September 9, 1982. Firm initiated recall
Distribution: Undetermined
Size & Quantity: 35,658 bottles were manufactured
Reason: Possible contamination with osmophilic yeast resulting in broken bottles.

Product: Quinidine Sulfate Tablets USP, 200 mg., an Rx drug used in the treatment of premature atrial and ventrical contractions, Recall #D-008-3
Code: Lot number 655-208, EXP 6/83
Manufacturer: Lederle Laboratories, Division American Cyanamid Company, Pearl River, New York
Recalled by: Manufacturer to the level of firm's distribution center, by telephone, September 29, 1982. Firm initiated recall complete
Distribution: Georgia, Illinois, Texas, Massachusetts
Size & Quantity: 2030/120 tablet bottles were distributed
Reason: Superpotency.

Product: Apple Juice from Concentrate, baby food product in 4.2 and 8 ounce jars, Recall #F-002-3
Code: All apple juice manufactured from January 1, 1982 through June 22, 1982 at Beech-Nut's Canajoharie, New York and San Jose, California facilities. First four digits in code are 2101 through and including 2622
Manufacturer: Beech-Nut Nutrition Corporation, Canajoharie, New York, from concentrate supplied by Universal Juice Company, New York, New York
Recalled by: Manufacturer, by telephone, followed by visits, October 15, 1982. Firm advises recall complete
Distribution: Nationwide
Size & Quantity: Unknown
Reason: Apple juice has been in whole or in part omitted.

Product: "Cox's" brand Tangy Corn Relish, Hot Chow Chow, Jalapeno Peppers (whole), Pickled Okra, Pickled Cauliflower, Pickled Carrots & Onions, Texas "Hot" Hot Sauce, "Hot" Tomato Relish, Chilibase, Stewbase and Bar-B-Que Sauce in 16 ounce, 32 ounce and one gallon jars, Recall #F-007/017-3
Code: All lots

Manufacturer: Cox's Relish Company, Daingerfield, Texas
Recalled by: Manufacturer, by telephone and letter, September 28, 1982. Firm initiated recall
Distribution: California, Arkansas, Louisiana, Mississippi, Nevada, Texas
Size & Quantity: Firm estimates 1000 cases 12/16 ounce jars, 100 cases 12/32 ounce jars and 150 cases 6/1 gallon jars remain on market
Reason: Swollen lids, inadequate processing.

Product: Pope Italian Peeled Tomatoes, 14 ounce cans, 24 cans per case, Recall #F-018-3
Code: B240, B243, B230, B250, B241, B234, B248, B252, B244 on one line and VC1 for all codes on the other line. Either line may be first
Manufacturer: Bormans Incorporated, Detroit, Michigan (distributor)
Recalled by: Distributor, by telephone, August 11, 1982. Firm initiated recall
Distribution: Michigan, Ohio
Size & Quantity: 1500 cases were distributed
Reason: Swollen cans.

Product: (a) Oreia II Dig. 50 tube kit. Enzyme Immunoassay for Digoxin, an in-vitro diagnostic, an EIA test kit for the quantitative measurement of digoxin in human serum or plasma. Kit has multiple components including calibrators; (b) Oreia II Dig. Digoxin Calibrator and Controls Kit. Enzyme Immunoassay for Digoxin for in-vitro diagnostic use. Intended for use with the preceding 50 tube kit product and other related products as additional calibrators and controls. Kit has multiple components including calibrators, Recall #T-003/004-3
Code: (a) Catalog #111F, lot #3181111; (b) catalog #111SC, lot #2481111
Manufacturer: Organon Inc., a part of Akzona Inc., West Orange, New Jersey
Recalled by: Manufacturer, by telephone and letter, August 30, 1982, September 2, 1982 and September 8, 1982. Firm initiated recall
Distribution: Nationwide and Canada
Size & Quantity: 98/50 tube kits; 39 calibrator/control kits were distributed
Reason: The 8 ng/ml calibrator vial components may have been incorrectly labeled as 4 ng/ml vials.

Complaints For Injunction Filed:

Against: Performance Products, Inc., St. Louis, Missouri
Product: Equidantin, a veterinary drug (82-257-221)
Charge: Product is a new animal drug marketed without an Approved New Animal Drug Application or notice of claimed investigational exemption
Filed: August 5, 1982 - U.S. District Court for the Eastern District of Missouri at St. Louis, Civil #82-1257C(A), INJ #1004

Seizure Actions Filed:

Product: Tomato Catsup (82-339-536)
Charge: Adulterated - Product consists in part of decomposed tomato material
Firm: KMC Foods, Inc., Cheriton, Virginia
Filed: August 27, 1982 - U.S. District Court for the District of Maryland at Baltimore; Civil #M-82-2545, FDC #63789.

Product: Foodtown Apple Juice (82-285-988 et al)
Charge: Misbranded - Product labeling is false and misleading; Adulterated - A valuable constituent, namely apple juice, has been in part omitted
Firm: Derry Products, Inc., Middletown, New York
Filed: October 7, 1982 - U.S. District Court for the Southern District of New York at New York City; Civil #82 Civ. 6654 (HFK), FDC #63814.

Product: Frozen Swordfish (82-252-262)
Charge: Adulterated - Product contains mercury in excess of 1.0 parts per million
Firm: Globe Fish Company, Boston, Massachusetts
Filed: October 15, 1982 - U.S. District Court for the Northern District of New York at Albany; Civil #82-CV-1110, FDC #63855.

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November 3, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	(a) Dr. Olbrich's Combinal Dye for Eyebrows and Eyelashes - Black; (b) Dr. Olbrich's Combinal Dye for Eyebrows and Eyelashes - Brown; (c) Dr. Olbrich's Combinal Dye for Eyebrows and Eyelashes - Blue; (d) Dr. Olbrich's Dye for Eyebrows and Eyelashes - Grey, in 0.25 ounce tubes, Recall #F-019/022-3
Code:	All lots
Manufacturer:	W. Pauli, Vienna, Austria
Recalled by:	Beauty Bazar, doing business as La Belle European Facial Salon, San Francisco (distributor), by letter, September 7, 1982. Firm initiated recall
Distribution:	California, Oregon
Size & Quantity:	Unknown
Reason:	Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

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NONE

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Amoxicillin for Oral Suspension, U.S.P. (Amoxicillin Trihydrate), 250 mg./5 ml., (150 ml. when mixed), an Rx antibiotic powder for reconstitution, Recall #D-009-3
Code: Lot #9089, EXP 4/86
Manufacturer: Biocraft Laboratories, Inc., Elmwood Park, New Jersey
Recalled by: Manufacturer, by telephone and letters, October 4, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates 2200 bottles remain on market
Reason: One bottle of a 150 ml. vial was labeled with a 100 ml. label. Reconstitution instructions direct for a lesser amount of water to be used which would result in superpotency.

Prosecution Actions Filed:

Against: Kings Trading, Inc., Kansas City, Missouri; and Jar-Yu King, President
Product: Sweet Sauce; Rice (82-261-628)
Charge: Adulterated with rodents
Filed: September 2, 1982 - U.S. District Court for the Western District of Missouri, Western Division at Kansas City; Criminal #82-00130-01/02-CR-W-9, FDC #63629.

Injunction Actions Filed:

Against: Best Pie Company, Inc., Seattle, Washington
Product: Various Bakery Products (82-278-872/874)
Charge: Adulterated - Products were held under insanitary conditions
Filed: September 10, 1982 - U.S. District Court for the Western District of Washington at Seattle; Civil #C82-10545V, INJ #1012.

Seizure Actions Filed:

Product: Apple Juice (82-312-332)
Charge: Adulterated - a valuable constituent, namely apple juice, has been in part omitted; Misbranded - article's labeling representing the product as being apple juice is false and misleading as applied to an article which does not consist wholly of apple juice
Firm: Natural Juice Manufacturing Company, Ltd., Tivoli, New York
Filed: October 12, 1982 - U.S. District Court for the District of New Jersey at Newark; Civil #82-3414, FDC #63847.

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FDA Enforcement Report

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November 10, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	R&H Liniment (formerly Camphorated Oil), for external use only, packed in 1 fluid ounce, 4 fluid ounce and 1 gallon bottles, Recall #D-012-3
Code:	All lots
Manufacturer:	Rush & Hebble Company, Inc., Indianapolis, Indiana
Recalled by:	Manufacturer, by letter, October 14, 1982, followed by telephone, October 18, 1982. Firm initiated recall
Distribution:	Central Indiana
Size & Quantity:	Firm estimates 250 gallons have been distributed
Reason:	The Federal Register announcement dated September 21, 1982 declared camphorated oil products marketed OTC for human use to be new drugs.

HE 20.4039:

Product: Kerr Insta-Char Ready to use Charcoal Suspension, 120 ml. and 250 ml., an Rx drug for absorption of toxic substances, Recall #D-014-3
Code: Lot Numbers "ZZ" and "ZX" (250 ml. bottles), "ZY" (120 ml. bottles)
Manufacturer: Crandall Associations, Inc., Warren, Michigan
Recalled by: Manufacturer, by telephone, October 13, 1982. Firm initiated recall
Distribution: Nationwide and Canada
Size & Quantity: 46 cases (25/250 ml. bottles) and 14 cases (25/120 ml. bottles) were distributed between September 11, 1982 and October 13, 1982
Reason: Product contaminated with salmonella.

Product: Jelco I.V. Catheter Plastic Hub Radiopaque, 20 gauge x 1 1/4 inch, single use, Recall #T-006-3
Code: Catalog #4056, sterility lot #1932 E4108, blister lot #1932 GIF
Manufacturer: Critikon, Inc., Southington, Connecticut
Recalled by: Critikon, Inc., Tampa, Florida, by telephone, September 23 and 24, 1982 with follow-up letter, mailed September 25, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 272 cartons/200 units each were distributed between September 8-14, 1982
Reason: Sterility of the product is compromised due to defective packaging.

Product: The Brewer Portascoot (alternative to an electric wheelchair), models #64050X-0, #65000X-0, Recall #T-007-3
Code: Serial numbers #6716 through #6920, #6992 through 7010
Manufacturer: E.F. Brewer Company, Menomonee Falls, Wisconsin
Recalled by: Manufacturer, by letter dated September 16, 1982. Firm initiated recall
Distribution: Nationwide, Canada, West Germany, Venezuela
Size & Quantity: 223 units were distributed
Reason: Possible defective/weak welds holding the mounting pin to a plate assembly which is attached to the front fork assembly.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Tega Donna Capsules, an Rx drug used to provide peripheral anticholinergic/antispasmodic action and mild sedation, Recall #D-010-3
Code: Lot number 8810
Manufacturer: Drummer Labs, Sellersville, Pennsylvania

Recalled by: Ortega Pharmaceutical Company, Inc., Jacksonville, Florida (distributor), by letter, August 9, 1982. Firm initiated recall complete
Distribution: North Carolina, South Carolina, Georgia, Florida
Size & Quantity: Firm estimates none remains on market
Reason: The label did not list FD&C Yellow #5 as an ingredient.

Product: Buffered Aspirin Tablets, 5 grains, in unit dose packets, 2 tablets/packet, an OTC drug, Recall #D-011-3
Code: B163312 and C291704 (manufacturer's assigned codes); 'S54' and 'Q08' (repacker's codes)
Manufacturer: Private Formulations, Inc., Edison, New Jersey
Recalled by: Manufacturer, by telephone and letter, October 1, 1982. Firm initiated recall
Distribution: Both lots were shipped in bulk to one repacker, Zee Medical Products Company, Inc., Irvine, California
Size & Quantity: 1,562,995 tablets of lot #B163312; 973,246 tablets of lot #C291704 were shipped
Reason: Batch No. B163312 (S54) tablets exceed the 3% USP limit for non-aspirin salicylates. Batch No. C291704 (Q08) tablets contain less than the 95% USP lower limit of the labeled amount of aspirin.

Product: ClaforanR (cefotaxime sodium) Powder for Reconstitution, an Rx drug for parenteral usage after reconstitution, a broad spectrum antibiotic, Recall #D-013-3
Code: Lot numbers A336/180112 EXP 3/84, A338/180132 EXP 3/84
Manufacturer: Hoechst AG, Frankfurt, West Germany
Recalled by: Hoechst-Roussel Pharmaceuticals, Inc., Somerville, New Jersey (U.S. distributor), by letter, October 15, 1982. Firm initiated recall
Distribution: Nationwide and Puerto Rico
Size & Quantity: Approximately 197,000 vials of both lots were distributed
Reason: Visible particulate matter in the solution after reconstitution.

Product: "Stat-Stain" - Rapid Staining Wright-Giemsa Modification, an in-vitro diagnostic used for staining white blood cells and bone marrow and has been modified to stain rapidly, in liquid form and packaged in 16, 32 and 128 ounce polyethylene bottles, Recall #T-009-3
Code: Catalog #48662-172, lot #60
Manufacturer: Volu-Sol Medical Industries, Inc., Las Vegas, Nevada
Recalled by: Manufacturer, by telephone, August 24, 1982 with follow-up letters, August 25, 1982. Firm initiated recall
Distribution: Nationwide, Israel
Size & Quantity: 54/16 ounce, 100/32 ounce, 25/128 ounce bottles are in commerce
Reason: This lot may not stain satisfactorily.

Product: Pharmaseal Spinal Anesthesia Trays with spinal anesthetic, spinal needle, 22 gauge, Recall #T-010-3
Code: Catalog number 4500C, lot number C2A076
Manufacturer: American Pharmaseal, Irwindale, California
Recalled by: American Pharmaseal, Glendale, California, by letter, April 2, 1982. Firm initiated recall complete
Distribution: Nationwide, Canada, Taiwan
Size & Quantity: Firm estimates none remains on market
Reason: Contents of trays are for continuous epidural procedure and should have been labeled as a continuous epidural anesthesia tray.

Product: Allergenic Extract (for diagnosis), House Dust Mixture in 5 ml. vials, Recall #B-003-3
Code: H36970M
Manufacturer: Hollister-Stier, Division of Cutter Laboratories, Inc., Spokane, Washington
Recalled by: Manufacturer, by letter, September 24, 1982. Firm initiated recall
Distribution: Nationwide, Canada, Japan, United Kingdom, West Indies
Size & Quantity: 226/5 ml. vials were distributed. Firm estimates 50 percent remains on market
Reason: The product label states that the vials contain 1,000 PNU/ml., whereas the vials actually contain 100 PNU/ml.

Seizure Actions Filed:

Product: Carbo-Lite/Calorex Tablets (82-276-607)
Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption
Firm: Vita-Lite Laboratories, Inc., Batesville, Arkansas and Bio-Tech Laboratories, Inc., Batesville, Arkansas
Filed: October 20, 1982 - U.S. District Court for the Eastern District of Tennessee; Civil #3-82-602, FDC #63820.

Product: Frozen Swordfish (82-252-486)
Charge: Adulterated - Product contains mercury in excess of 1.0 parts per million
Firm: Crocker & Winsor Seafoods, Boston, Massachusetts
Filed: November 3, 1982 - U.S. District Court for the Western District of New York at Buffalo; Civil #82-1020, FDC #63875.

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FDA Enforcement Report

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November 17, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

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Product:	Sheffield Stoneware Dinner Plates and Salad/Sandwich Plates with strawberries design, Recall #F-024-3
Code:	Dinner plates - ART code "SC-1" (shipping cases); Salad/Sandwich plates - ART code "SC-12" (shipping case)
Manufacturer:	SCT Company, Ltd., Bangkok, Thailand
Recalled by:	National Tea Company, Harahan, Louisiana, by pick-up, September 29, 1982. Firm initiated recall
Distribution:	Louisiana, Mississippi
Size & Quantity:	18,720 dinner plates and 1,248 salad/sandwich plates were distributed
Reason:	Lead and cadmium contamination.

HE 20.4039:

Product: "Hemed CVAC-120 Central Venous Access Catheter 6.6-French Radiopaque Tubing with one dacron cuff H-810-009 5/19/82" "Use Before JUL 1983"; "HEMED CVAC - 220 Central Venous Access Catheter 9.5 - French Radiopaque Tubing with one Dacron Cuff H-810-010 5/19/82" "Use Before JUL 1983," Recall #T-008-3
Code: CVAC 120 - Lot #6820 6001; CVAC 220 - lot #6820 5029
Manufacturer: DLP, Inc., Walker, Michigan
Recalled by: Hemed, Inc., Placentia, California (distributor), by telephone, September 1, 1982 and letter, September 1, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 72 units of lot CVAC-120 #6820 6001 and 332 units of CVAC-220 lot #6820 5029 were distributed. Firm estimates 25 percent remains on market
Reason: The female leur hub developed cracks when attached to male fitting.

Product: "GEE/O.P.G. Ocular Pneumo Plethysmograph," Model No. OPG-4, used to measure ocular pressure, screen patients for hemodynamically significant carotid artery stenosis and occlusion, Recall #T-011-3
Code: Serial numbers 101 through 573 and serial number 575, Model OPG-4
Manufacturer: Electro-Diagnostic Instruments, Burbank, California
Recalled by: Manufacturer, by letter, September 21, 1982. Firm initiated recall
Distribution: Nationwide, Holland, The Philippines, Spain, United Kingdom, Belgium, Australia
Size & Quantity: 473 units were distributed. Firm estimates 99% remain on market
Reason: The arm assembly that supports the transducer head of the GEE/O.P.G. failed at the upper and lower end.

Product: TSI Agar Slants (triple sugar iron), an in-vitro diagnostic culture media for single biochemical test, packaged in 8 ml. glass test tubes with plastic screw top, Recall #T-013-3
Code: Lot #318821, EXP 9/82
Manufacturer: Microbiological Media, San Ramon, California
Recalled by: Manufacturer, by telephone with follow-up letter, August 31, 1982. Firm initiated recall
Distribution: Northern California
Size & Quantity: 160 units were distributed
Reason: The culture media is nonfunctional for its intended use. The pH falls below the limits of acceptability due to lack of stability of the culture media.

Class III - ***A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)***

Product: Cal-Block Tablets (starch blocker), in 30 tablet bottles, each tablet contains 500 mg. of a natural protein concentrate and phaseolamin, Recall #D-016-3
Code: Lot #101
Manufacturer: Unknown
Recalled by: Local Beauty Supply, Inc., Indianapolis, Indiana, by memo dated October 6, 1982. Firm initiated recall
Distribution: Indiana, Ohio
Size & Quantity: Firm estimates 480/30 tablet bottles remain on market
Reason: Product is a new drug marketed without an approved New Drug Application.

Product: Osco Vitamin C Tablets, ascorbic acid, 250 mg., an oral vitamin food supplement in 100 tablet amber plastic bottles, Recall #F-023-3
Code: Lot #I301A, I301B, L031A, L031B
Manufacturer: Freshlabs, Inc., Warren, Michigan
Recalled by: Jewel Company, Inc., Chicago, Illinois, by telephone October 25, 1982, and follow-up letter, October 26, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 20,304 bottles were distributed. Firm estimates very little remains on market
Reason: Vitamin C tablets labeled as capsules.

Product: Folger's Instant Coffee Crystals, packaged in 2 ounce jars, Recall #F-025-3
Code: N2225, N2245
Manufacturer: The Folger Coffee Company, New Orleans, Louisiana
Recalled by: The Proctor & Gamble Company, Cincinnati, Ohio, by letter, October 27, 1982. Firm initiated recall
Distribution: Southeastern and North Central United States, New York, California, Utah
Size & Quantity: Firm estimates 1,000-1,500 cases remain on market
Reason: Short weight.

Seizure Actions Filed:

Product: Tomato Paste (83-252-578)
Charge: Adulterated - Product contains decomposed tomato material
Firm: Cicatrade of Brazil, Brazil
Filed: November 4, 1982 - U.S. District Court for the Western District of New York at Buffalo, Civil #82-1025, FDC #63890.

Disposition of Injunctions:

Defendants: Tablicaps, Inc., and Bela Jancsik at Trenton, New Jersey, District of New Jersey
Nature of Charges: Noncompliance with current Good Manufacturing Practice Regulations
Disposition: Permanent injunction prohibiting all manufacture or shipment of drugs until the firm complies with FDA's Good Manufacturing Practice Regulations.

Disposition of Civil Penalty:

Defendants: Diagnostic Instruments Corporation, and Rudolph J. Chioda, president
Nature of Charges: Failure to comply with requirements of the Radiation Control for Health and Safety Act with respect to diagnostic X-ray systems and that the defendants failed to file a corrective action plan following notification of defects and failed to file other required reports
Disposition: Consent decree of civil penalty. President fined $2,500; also the decree prohibits the individual from ever engaging in the business of manufacturing, assembling, or installing X-ray units or other electronic products without written permission from the agency.

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November 24, 1982

Recalls and Field Corrections:

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Product:	Permalash Eyelash/Eyebrow Dye, black and brown, Recall #F-100/101-3
Code:	All codes
Manufacturer:	Zena Cosmetic Company, London, England
Recalled by:	Faces Enterprises Ltd., Towson, Maryland (importer/distributor), by telephone, October 7, 1982. Firm initiated recall complete
Distribution:	Baltimore-Metropolitan area
Size & Quantity:	Firm estimates none remains on market
Reason:	Products contain coal tar ingredients which may cause permanent injury to eyes, including blindness.

Product:	Revital products in powder and gel forms. The powder form is in a 12 gram plastic container. The gel is in a 55 gram tube. Both products are used primarily for healing open wounds, Recall #T-001-3
Code:	All codes under all labels
Manufacturer:	Robertson Resources, Ltd., Salisbury, Maryland
Recalled by:	Manufacturer, by letter dated November 5, 1982. FDA requested recall. See FDA talk papers T82-30, April 29, 1982 and T82-74, October 28, 1982.
Distribution:	Nationwide
Size & Quantity:	Unknown
Reason:	Bacteriological contamination.

HE 20.4039:

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Product: "Schilling" Brand of Allspice GD, Arrowroot, Basil Lvs. Sweet, Bay Leaves, Bell Pepper Flakes, Bonappetit, Caraway Seed, Celery Salt, Celery Seed, Chervil, Chili Powder, Chives Freeze Dried, Cinnamon GD, Cinnamon Stick, Cloves WH, Cloves GD, Cream of Tartar, Cumin GR, Cumin Seed, Curry PWDR, Dill Seed, Dill Weed, Fennel Seed, Garlic PWDR,Garlic Minced, Garlic Salt, Ginger GD, Ginger WH, Herb Seas, Horse Radish PWD, Italian Seas, Lemon Herb GARN, Lemon Peel, Marjoram Leaves, Meat Ten Plain, Mint Flakes, MSG, Mustard GD, Nutmeg GD, Onion PWDR, Onion Salt, Onion Minced, Oregano GD, Oregano Leaves, Orange Peel, Paprika, Parsley Flakes, Cracked Pepper, Coarse GD Pepper, Ground Pepper, Crushed Red Pepper, WH Lampong Pepper, Seas Pepper Medfly, White Pepper, GD Red Pepper, Pickling Spice, Poppy Seed, Poultry Seas, Pumpkin Pie Spice, Rosemary Leaves, Sage GD, Sage Rubbed, Salad Herbs, Saffron, Savory GD, Seasonall, Sesame Seed, Smoked Salt, Tarragon Leaves, Thyme GD, Thyme Leaves, Vanilla Beans, Vegetable Delight, Recall #F-026/098-3

Code: Lot #7257 through 7430 inclusive

Manufacturer: McCormick & Company, Inc., Schilling Plant, Salinas, California

Recalled by: Headquarters, McCormick & Company, Inc., Hunt Valley, Maryland, by letter during the week of October 4, 1982. Firm initiated recall

Distribution: All states west of the Mississippi

Size & Quantity: 166,828 dozen bottles were distributed

Reason: Firm reported approximately 1% of the bottles of each item to contain a chip or crack at the top of the jar under the threads of the plastic caps.

Product: Harris Atlantic Minced Crab Meat and Generic Brand Minced Crab Meat, net weight 6 1/2 ounces, Recall #F-099-3

Code: All production in 1979, 1980, 1981, 1982. The first two digits of the code would be BY, BZ, BA or BB followed by a three digit number

Manufacturer: Blue Channel Corporation, Belhaven, North Carolina

Recalled by: Blue Channel Corporation, Port Royal, South Carolina, by letter, July 16, 1982. Firm initiated recall

Distribution: Nationwide

Size & Quantity: 66,656 dozen cans were distributed

Reason: Swollen cans.

Product: CPI Command P5 Model 0630 Multi-Programmable Pulse Generator, Recall #T-005-3

Code: Serial numbers 247551, 249720, 249737, 250214, 250644, 252275, 249716

Manufacturer: Cardiac Pacemakers, Inc., St. Paul, Minnesota

Recalled by: Manufacturer, by letter, September 29, 1982. Firm initiated recall

Distribution: Arizona, California, Nebraska, Pennsylvania, Illinois, Maryland, New York

Size & Quantity: 9 units had been implanted; 7 units remain implanted.

Reason: Units labeled as bipolar have unipolar characteristics including susceptibility to muscle stimulation and possible external and myocardial interference with pacer function. Problem caused by improper wiring on the printed circuit board.

Product: "Bardic" and "Higgs" Plastic Foley Catheters with Rubber Balloon Tips, used for bladder catheterization, Recall #T-016-3

Code: All lots of the following catalog numbers:

BARDIC:	HIGGS:	SIZE:
145S	014501	12-14 French
145M	014502	16-18 French
145L	014503	20-22 French
146M	014602	16-18 French
146L	014603	20-22 French
146XL	014604	24-26 French

Manufacturer: Davol, Inc., Providence, Rhode Island (contract assembler); C.R. Bard, Urological Division, Murray Hill, New Jersey

Recalled by: C.R. Bard, Inc., Murray Hill, New Jersey, by letter dated October 14, 1982. Firm initiated recall

Distribution: Nationwide and Canada

Size & Quantity: Firm estimates less than 200 units remain on market

Reason: Device may exhibit brittleness and a tendency to fragment during use.

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Product: Sober Up Time, 3 tablets/packet, 24 packets/box. Product purports to minimize inebriation, Recall #D-015-3

Code: Not coded

Manufacturer: Rajar Enterprises, Inc., San Juan Capistrano, California

Recalled by: Its Sober Up Time, Chatsworth, California (distributor), by telephone, October 27, 1982. Firm initiated recall

Distribution: California, Nevada, Arizona

Size & Quantity: Firm estimates 20 cases/18 boxes/24 packets remain on market

Reason: Product is a new drug marketed without an approved New Drug Application.

Seizure Actions Filed:

Product: Capsules (82-310-187)
Charge: Adulterated (all lots) - Products are being held in non-conformity with current good manufacturing practices since they are being held for sale beyond their labeled expiration dates; counterfeit (certain articles)
Firm: Z & J's Distributors, Charles Town, West Virginia
Filed: October 14, 1982 - U.S. District Court for the Northern District of West Virginia at Martinsburg; Civil #82-29-M, FDC #63869.

Product: Pink Pepper Berries (82-283-739)
Charge: Adulterated - Product contains a poisonous deleterious substance, namely pink pepper berries (Schinus terebinthifolius), which renders it injurious to health
Firm: American Roland Food Corp., Inc., East Rutherford, New Jersey
Filed: October 15, 1982 - U.S. District Court for the Eastern District of Virginia at Alexandria; Civil #82-0961-A, FDC #63860.

Product: 3-Way OTC Look-Alikes (82-299-585)
Charge: Products are new drugs marketed without approved New Drug Applications or notices of claimed investigational exemption
Firm: (In possession of) Midwest Pharmaceuticals Inc., Omaha, Nebraska
Filed: October 26, 1982 - U.S. District Court for the District of Nebraska; Civil #82-O-574, FDC #63883.

Product: Starch Blocker Tablets (82-275-494)
Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption; Misbranded - Product lacks adequate directions for use
Firm: Bio-Tech Laboratories, Inc., Batesville, Arkansas
Filed: October 22, 1982 - U.S. District Court for the Middle District of Tennessee at Nashville,; Civil #82-3911, FDC #63837.

Product: OTC "Look-Alike" Drugs (82-309-437)
Charge: Products are new drugs marketed without approved New Drug Applications or notices of claimed investigational exemption; Misbranded - Products lack adequate directions for use
Firm: B. T. Products, Inc., St. Petersburg, Florida
Filed: October 29, 1982 - U.S. District Court for the Western District of Michigan at Grand Rapids; Civil #G82-843CA1, FDC #63868.

Product: Natural Starch Blockers (82-391-900)
Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption; Misbranded - Product lacks adequate directions for use
Firm: Pharmaceutical Dynamics, Inc., Hauppage, New York
Filed: November 15, 1982 - U.S. District Court for the Eastern District of Michigan, Southern Division; Civil #82-40468, FDC #63881.

Product: OTC "Look-Alike" Drugs(83-391-661)
Charge: Products are new drugs marketed without approved New Drug Applications or notices of claimed investigational exemption; Misbranded - Product lacks adequate directions for use
Firm: Pharmaceutical Dynamics, Inc., Hauppage, New York
Filed: November 15, 1982 - U.S. District Court for the Eastern District of Michigan, Southern Division at Flint; Civil #82-40467, FDC #63889.

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

December 1, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

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Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Alta Dena Certified Raw Milk in 1/2 gallon and 1 quart sizes and Non-Fat Milk in 1/2 gallon and 1 quart sizes, Recall #F-102-3
Code:	All codes from herds C, D, E
Manufacturer:	Alta-Dena Certified Dairy, City of Industry, California
Recalled by:	Glen O. Barker & Son Enterprises, doing business as The Health Run, Sacramento, California, by telephone, August 4, 1982. Firm initiated recall complete
Distribution:	Northern California, Nevada
Size & Quantity:	(a) 192 cases (12 cartons/case) of 1/2 gallon size and 14 cases (24 cartons/case) of 1 quart size; (b) 6 cases (12 cartons/case) of 1/2 gallon size and 17 cases (24 cartons/case) of 1 quart size of the milk were distributed
Reason:	Salmonella contamination.

HE 20.4039:

Product: Malossol WWG Caspian Beluga Caviar and Malossol WWG Caspian Sevruga Caviar in 100, 200, 400 gram cans, Recall #F-103/104-3
Code: Not coded
Manufacturer: W.G. White, Inc., Walnut, California (importer/repacker)
Recalled by: Importer/repacker, by telephone, October 22, 1982. Firm initiated recall
Distribution: California
Size & Quantity: Firm estimates 20 pounds in various size cans remain on market
Reason: Products contain borates, a nonpermitted food additive.

Product: Twin-90 0.22 Micron Filter unit used to remove any microorganisms and also to filter water, culture media, irrigation solutions, intravenous solutions and antibiotic solutions, Recall #T-014-3
Code: Catalog #PMGS 09002, code numbers C2H43712, C2J58238, C2J58735, C2J59597, C2J61686, C2K61687
Manufacturer: Millipore Corporation, Jaffrey, New Hampshire
Recalled by: Millipore Corporation, Bedford, Massachusetts, by letter and telex, October 13, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: Estimates indicate 2000 units remain on market
Reason: The filters have developed cracks which could cause a failure of the device to remove microorganisms from the fluid stream.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Cholesterol Reagent Strips, an in-vitro diagnostic for use with Ames Seralyzer Reflectance Photometer, for the quantitative determination of serum cholesterol, packed in bottles of 25 and 50 strips, Recall #T-015-3
Code: Lot #0123042
Manufacturer: Miles Laboratories Inc., Ames Division, Elkhart, Indiana
Recalled by: Manufacturer, by letter dated October 8, 1982. Firm initiated recall
Distribution: Nationwide and international
Size & Quantity: 2,020/50 strip bottles and 3,696/25 strip bottles were distributed between May 21, 1982 and September 28, 1982
Reason: Strips have degraded (do not react properly during use). The firm has determined that the product is losing reactivity quickly. This would result in failure of the Seralyzer instrument to calibrate using the product.

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December 8, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product:	Baker Instrument 100 series Cell Counters, hematology, model series numbers 121, 130, 131, 150, Recall #T-017-3
Code:	Various serial numbers on individual units: 506139, 150195, 306107, 150250, 150294, 150285, 130151, 150320, 506115, 306123, 305103, 150153, 506131, 150193, 130143, 150111, 506156, 506130, 306103, 506143, 150225, 130145, 131057, 306112, 506137, 150142, 130152, 150181, 150276, 130156, 130153, 150283, 150293, 130146, 150296, 506138, 150235, 150295, 130119, 150322, 150307, 506145, 305107, 506128, 150287, 506132, 150267, 150303, 150299, 150315, 150234, 150324, 150317, 150323, 150200, 130144, 150304, 306102, 150193
Manufacturer:	Baker Instruments Corporation, Bethlehem, Pennsylvania
Recalled by:	Manufacturer, by telephone and letter, October 15, 1982. Firm initiated recall
Distribution:	Nationwide and international
Size & Quantity:	114 units were distributed

HE 20.4039:

Reason: The counter of WBC's (white blood cells) only registered up to a 100,000 count; the counter then reverted back to "0" and started over without any indication that 100,000 WBC's had been reached.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Osco Drug Vitamin B1, 100 mg. Tablets, a dietary supplement in 100 tablet bottles, Recall #F-105-3
Code: Lot numbers G291A, I021A, I031A
Manufacturer: Freshlab Inc., Warren, Michigan
Recalled by: The Park Corporation, Division of Jewel Company, Barrington, Illinois (repacker), by letter, November 2, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 7,632 bottles were distributed
Reason: Tablets labeled as capsules.

Product: B & M Brick Oven Baked Beans, small pea beans with pork in brown sugar sauce, 21 ounce can, Recall #F-106-3
Code: -AE/1382, -AE/1392
Manufacturer: William Underwood Company, Burnham & Morrill Division, Portland, Maine
Recalled by: William Underwood Company, Westwood, Massachusetts, by telephone, September 24, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 5907 cases/24 cans, lot -AE/1382 and 6491 cases/24 cans, -AE/1392 were distributed
Reason: Swollen and leaking cans.

Product: Nature's Finest Pantothenic Acid Tablets, 100 mg. and 250 mg.; Walgreen's Finest Pantothenic Acid Tablets, 250 mg., in 100 tablet bottles, Recall #F-107 108-3
Code: Lot #8906D40 and AUCI (Nature's Finest 100 mg.), Lot 7157D10 (Nature's Finest 250 mg.), Lot #8593D92 (Walgreen's 250 mg.)
Manufacturer: Walgreen Laboratories, Inc., Subsidiary of Walgreen Co., Chicago, Illinois
Recalled by: Walgreen Company, Deerfield, Illinois, by computer line notification, October 27-28, 1982 and store bulletin, November 2, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: 17,136 bottles of 100 mg. and 9,036 bottles of 250 mg. tablets were distributed
Reason: Tablets contain isopropyl alcohol.

Seizure Actions Filed:

Product: Starch Blocker Tablets (82-275-513)
Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption
Firm: Bio-Tech Laboratories, Inc., Batesville, Arkansas and Vita-Lite Laboratories, Inc., Batesville, Arkansas
Filed: October 29, 1982 - U.S. District Court for the Western District of Tennessee; Civil #82-2822-W, FDC #63819.

Product: Starch Blocker Tablets (82-276-766)
Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption
Firm: Bio-Tech Laboratories, Inc., Batesville, Arkansas and Vita-Lite Laboratories, Inc., Batesville, Arkansas
Filed: October 29, 1982 - U.S. District Court for the Western District of Tennessee; Civil #82-2823-W, FDC #63821.

Product: Starch Blocker Tablets (82-276-764)
Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption
Firm: Vita-Lite Laboratories, Inc., Batesville, Arkansas and Bio-Tech Laboratories, Inc., Batesville, Arkansas
Filed: October 29, 1982 - U.S. District Court for the Western District of Tennessee; Civil #82-2826-W, FDC #63824.

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FDA Enforcement Report

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

December 15, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	Extracorporeal Models DM-350 (domestic) and DM-350-1 (international) Single Patient Systems (SPS) Hemodialysis Machines, Recall #T-012-3
Code:	Serial numbers 5464 through 14018
Manufacturer:	Extracorporeal, Inc., Pinellas Park, Florida
Recalled by:	Extracorporeal, Inc., King of Prussia, Pennsylvania, by letter, September 17, 1982 and a follow-up letter to non-respondents, September 28, 1982. Firm initiated field correction
Distribution:	Nationwide and international
Size & Quantity:	3215 units were distributed
Reason:	The Model 121 Supply/Bypass Solenoid Valve used in these SPS machines may fail to divert an appropriate dialysate during conductivity or temperature alarm as intended.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

HE 20.4039:

Product: Bush's Best Chili Hot Beans, net weight 16 ounces, Recall #F-114-3
Code: 11925/CHIL2, 11926/CHIL2
Manufacturer: Bush Brothers & Company-Blytheville Plant, Blytheville, Arkansas
Recalled by: Manufacturer, by telephone and follow-up letters, March 19, 1982. Firm initiated recall complete.
Distribution: Alabama, Arkansas, Florida, Illinois, Indiana, Kentucky, Louisiana, Missouri, Mississippi
Size & Quantity: 4,794 cases, 24/16 ounce containers were distributed
Reason: Swollen cans.

Product: Rovite Tonic, an Rx drug containing pentylenetetrazol in 1 pint containers, Recall #D-017-3
Code: All lots
Manufacturer: Mikart, Inc., Atlanta, Georgia
Recalled by: Jack Eckerd Corporation, Clearwater, Florida, by letter dated October 19, 1982. Firm initiated recall
Distribution: Florida and south Georgia
Size & Quantity: Firm estimates 85 bottles remain on market
Reason: Product marketed without an approved New Drug Application.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Chocolate flavored ice cream syrup in #10 cans (8 pound 2 ounces) under the Johnston or Swensen Ice Cream label, Recall #F-109-3
Code: Can code 31246/20503, Swenson case code 20503, Johnston case code 20329
Manufacturer: Ward-Johnston, Inc., Division of the Terson Company, Inc., Milwaukee, Wisconsin
Recalled by: Manufacturer, by telephone, July 2, 1982 Swenson label and extended to include Johnston labeled product on September 7, 1982. Firm initiated recall
Distribution: New Jersey, Texas, California, New York, Pennsylvania
Size & Quantity: 129 cases were shipped
Reason: Swollen cans.

Product: (a) Vitex brand Vitamin A 50-II, a liquid vitamin A concentrate, used only in dairies for fortification of milk, packaged in 500 ml. plastic bottles; (b) Vitex brand Vitamin A-D 50-II, a liquid vitamin A and D concentrate, used only in dairies for fortification of milk, packaged in 500 ml. plastic bottles; and Vitex brand Vitamin A-D 375-II, a liquid vitamin A and D concentrate, used only in dairies for fortification of milk, packaged in 1 gallon plastic jugs, Recall #F-110/111-3

Code: Lot numbers - (a) 2872; (b) 44K2722, 2722, 2952 and 22K226, 23K226
Manufacturer: Vitex/Richardson & Holland Division of Mallinckrodt, Inc., Seattle, Washington
Recalled by: Manufacturer, by letter, November 1, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: (a) 6,367/500 ml. bottles; (b) 13,237/500 ml. bottles and 658/1 gallon jugs were distributed
Reason: Subpotent in vitamin A.

Product: Spirulina Plus Tablets, 500 mg., Recall #F-112-3
Code: Not coded
Manufacturer: Private Formulations, Inc., Edison, New Jersey
Recalled by: Manufacturer, by visit, November 15, 1982. Firm initiated recall
Distribution: One consignee in New York
Size & Quantity: 2,899,547 tablets were distributed
Reason: Tablets manufactured from spirulina containing insect and feather fragments.

Product: Spirulina "Plankton" Tablets, 500 mg, 30,000 tablets per carton, Recall #F-113-3
Code: Lot #3981, date 9/17/82
Manufacturer: Proteins Plus, Inc., Fairfield, New Jersey
Recalled by: Manufacturer, by visit, November 12, 1982. Firm initiated recall
Distribution: One consignee in New Jersey
Size & Quantity: 2 cartons (30,000 tablets/carton) were distributed
Reason: Tablets manufactured from spirulina containing insect and feather fragments.

Product: Date-Walnut-Raisin All Natural Lowfat Yogurt, Recall #F-115-3
Code: Product has a 30-day pull date
Manufacturer: Bison Foods Company, Buffalo, New York
Recalled by: Manufacturer, by telephone and driver pick-up, November 2, 1982. Firm initiated recall
Distribution: Most of the product was shipped to Giant Food, Inc., Landover, Maryland with a small portion to western New York
Size & Quantity: Firm estimates 600 cases of 12/8 ounce containers at wholesale and approximately 130 cases at the retail level
Reason: The date-walnut-raisin ingredient used to manufacture the product is adulterated with insects.

Product: Bentley's PF 302 Biologic Gas Line Filter, provides for the removal of bacteria and debris from the oxygenated gas used during bypass surgery. The filter is marketed primarily as a component of a custom made tubing set for perfusing, an Rx device, Recall #T-020-3
Code: PF 302 all codes, all lots
Manufacturer: Bentley Laboratories, Irvine, California
Recalled by: Manufacturer, by letter dated October 11, 1982. Firm initiated recall
Distribution: Nationwide
Size & Quantity: Firm estimates 5,000 remain on market
Reason: During manufacturing, some filters were damaged by a QC test which destroyed the filtering potential of the membrane.

Product: Panoramic dental X-ray unit estimated to be in daily use, Recall #R-025-2
Code: Model number PT75
Manufacturer: Syntex Dental Products, Inc., Den-Tal-Ez X-ray Equipment, Des Moines, Iowa
Recalled by: Manufacturer. FDA approved the firm's corrective action plan on August 12, 1982. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: 636 units were distributed and all should now be corrected
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968.

Seizure Actions Filed:

Product: Starch Blocker Tablets (82-276-768)
Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption
Firm: Bio-Tech Laboratories, Inc., Batesville, Arkansas
Filed: October 29, 1982 - U.S. District Court for the Western District of Tennessee; Civil #82-2825-W, FDC #63822.

Product: Starch Blocker Tablets (82-276-770)
Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption
Firm: Vita-Lite Laboratories, Inc., Batesville, Arkansas and Bio-Tech Laboratories, Inc., Batesville, Arkansas
Filed: October 29, 1982 - U.S. District Court for the Western District of Tennessee; Civil #82-2824-W, FDC #63823.

Product: Mister Max Rawhide Bone and/or Chips (82-345-872)
Charge: Adulterated - Product contains an unidentified deleterious substance in such quantity which may render it injurious to health
Firm: Insu Corporation, Ltd., San Francisco, California (shipper)
Filed: November 23, 1982 - U.S. District Court for the Northern District of California at San Francisco; Civil #C-82-6439-MHP, FDC #63877.

Product: OTC "Look Alike" Drugs (83-276-532)
Charge: Products are new drugs marketed without approved New Drug Applications or notices of claimed investigational exemption and labels lack adequate directions for use
Firm: Stimcap, Inc., Louisville, Kentucky
Filed: November 29, 1982 - U.S. District Court for the Western District of Kentucky at Louisville; Civil #C82-0708-L(B), FDC #63887.

Product: Tomato Paste (83-351-481)
Charge: Adulterated - Product contains decomposed tomato material
Firm: (In possession of) Cliffstar Corporation, Dunkirk, New York
Filed: December 3, 1982 - U.S. District Court for the Western District of New York at Buffalo; Civil #82-1114, FDC #63911.

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RECALL: Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.

December 22, 1982

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

NONE

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: (a) Regular Potato Chips; (b) Wavy Potato Chips; (c) Green Onion Potato Chips; (d) Barbecue Potato Chips; (e) Cheese Popcorn; (f) Buttered Popcorn; (g) Cheese Curl; (h) Corn Chips; (i) Carmel Corn; (j) Nacho Crackers (k) Potato Skins; (l) Pretzels, Recall #F-117/128-3
Code: Commingled lots, codes could not be determined
Manufacturer: Husman Snack Foods, Cincinnati, Ohio
Recalled by: Manufacturer, by visit, November 6, 1982. Firm initiated recall complete
Distribution: Ohio
Size & Quantity: Firm estimates none remains on market
Reason: Xylene (solvent) contamination.

HE 20.4039:

Product: Vending Machines containing one of the following: (a) "Penny Candy;" (b) Chewing Gum; (c) Candy-Coated Peanuts, the products ordinarily sell for one cent, and are displayed within glass "globes" bearing the "Ford" brand name, Recall #F-129-3

Code: All machines and foods distributed prior to December 2, 1982

Manufacturer: Ford Gum & Machine Company, Inc., Akron, New York

Recalled by: Manufacturer, by letter, December 2, 1982. Firm initiated field correction

Distribution: Nationwide

Size & Quantity: Over 100,000 vending machines are subject to field correction

Reason: Machine labeling fails to declare the presence of FD&C Yellow #5 in each of the products.

Product: Davol Thora-Klex Collection/Chest Drainage Unit, used to drain fluid or air from chest cavity via application of negative pressure, 8 units/carton, Recall #T-021-3

Code: Product code 7750, all lots manufactured between August 1981 through November 2, 1982

Manufacturer: Davol, Inc. C.S.C., Englewood, Colorado

Recalled by: Davol, Inc., Cranston, Rhode Island, by telephone and letter, November 17, 1982. Firm initiated recall

Distribution: Nationwide

Size & Quantity: Firm estimates 10,000 remain on market

Reason: The product is unable to maintain sufficient negative pressure when used as a gravity drainage device.

Product: Source Plasma (Human), for manufacturing use only, Recall #B-004-3

Code: 2P435, 2P1894, 2P4436

Manufacturer: Mid-South Blood Services, Inc., Louisville, Kentucky

Recalled by: Manufacturer, by letter, October 12, 1982. Firm initiated recall

Distribution: Vienna, Austria

Size & Quantity: 218 units

Reason: Two hundred eighteen (218) units were collected from three donors who had previously tested reactive for the hepatitis B surface antigen (HBsAg).

Product: Mikrox Cabinet X-Ray Systems, part number 103150, Recall #R-001-3

Code: Serial numbers 1 through 8 introduced into commerce prior to July 1982

Manufacturer: Nicolet XRD Corporation, Fremont, California

Recalled by: Manufacturer. FDA approved the firm's corrective action plan February 29, 1982. Firm initiated field correction

Distribution: California, Missouri, Indiana, Pennsylvania, Texas, France West Germany

Size & Quantity: 8 units are subject to field correction
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968. Each of these units have no primary disconnect switch and lack two independent means of indicating X-ray production. Further the first three units also exceeded the radiation emission limit as required by law.

Product: A mobile radiographic system, Recall #R-005-3
Code: Model number MC125L-30
Manufacturer: Shimadzu Precision, Japan
Recalled by: CGR Medical Corporation, Baltimore, Maryland (importer). FDA approved the firm's corrective action plan on December 2, 1982. Firm initiated field correction
Distribution: Nationwide
Size & Quantity: 42 units are subject to field correction
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968. The noncompliances were with the reproducibility, beam quality, mAs accuracy, and user information (line current, duty, cycle pKv measurement basis, mAs accuracy statement and pKv used to determine HVL) sections of the diagnostic X-ray standard.

Product: Omni 325 Mobile C-Arm X-Ray System, Recall #R-006-3
Code: P/N 55509G product, manufactured from December 1980 through April 1982
Manufacturer: Fischer Imaging Corporation, Franklin Park, Illinois
Recalled by: Manufacturer, by letter dated September 16, 1982. Firm initiated field correction
Distribution: Unknown
Size & Quantity: 31 units subject to field correction
Reason: Noncompliance with FDA performance standard under the Radiation Control for Health and Safety Act of 1968 in that the beam limiting device (BLD) in use on product was not operating in compliance with the requirement of the law and that inaccuracy of kV and mA could lead to lack of reproducibility.

Class III - *A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)*

Product: Drinking Water in 8 fluid ounce cartons under the following labels: Santa Fe, Cotton Belt Route, Union Pacific, Adams Ale, intended for use by train and mining crews, Recall #F-132-3
Code: Expiration dates are SEP 82, OCT 82, NOV 82, DEC 82, JAN 83, FEB 83, MAR 83
Manufacturer: All Star Dairy, Special Products Division of Milk Producers Marketing Company, Kansas City, Kansas
Recalled by: Milk Producers Marketing Company, Lawrence, Kansas, by telephone, over the last 60 days. Firm initiated recall complete
Distribution: Missouri, Kansas, New Mexico
Size & Quantity: Firm estimates none remains on market
Reason: Leaking cartons.

Product: Bumble Bee Brand Chunk White Tuna in Oil, packed in 6 1/2 ounce metal cans, 48 cans/case, Recall #F-133-3
Code: 32-96/8J2C
Manufacturer: Bumble Bee Puerto Rico, Inc., Mayaguez, Puerto Rico
Recalled by: Castle & Cooke Foods, San Francisco, California, by pick-up, October 21, 1982. Firm initiated recall
Distribution: Maryland, New Jersey, Ohio
Size & Quantity: 359 cases were shipped
Reason: Decomposition.

Seizure Actions Filed:

Product: Date, Raisin, Walnut Yogurt (83-330-277/8)
Charge: Adulterated - Product contains insects and insect fragments
Firm: Ramsey Laboratories, Inc., Cleveland, Ohio
Filed: December 8, 1982 - U.S. District Court for the Western District of New York at Buffalo; Civil #82-1124, FDC #63904.

Product: Advantage *** Starch Blocker Protein Concentrate (83-350-886)
Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption
Firm: General Nutrition Centers, Pittsburgh, Pennsylvania
Filed: December 10, 1982 - U.S. District Court for the Western District of New York at Buffalo; Civil #82-1144E, FDC #63905.

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December 29, 1982

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Product:	Swan Camphorated Oil, 2 fluid ounces, an OTC topical drug product, Recall #D-019-3
Code:	All lots distributed and shipped between January 1, 1982 through September 28, 1982
Manufacturer:	CMC Inc., Smyrna, Tennessee
Recalled by:	Manufacturer, by letter dated September 28, 1982. FDA requested recall
Distribution:	Nationwide and Puerto Rico
Size & Quantity:	1211 cases (72 bottles/case) were shipped
Reason:	FEDERAL REGISTER announcement (21 CFR 310.526) dated September 21, 1982, declared camphorated oil products marketed OTC for human use to be new drugs.

HE 20. 4039:

Class III - ***A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. (Class III recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information of the progress of recalls.)***

Product: One Percent Silver Sulfadiazine Cream, an Rx topical anti-infective used in the treatment of burns to prevent infection, 50 gram jars, packaged 6 jars/carton and 24 cartons/shipping case, Recall #D-018-3
Code: Lot numbers IS800A1, OS800A6, 4S800A9, 3S800F9, 3S800F9A, 7S800H2
Manufacturer: Paco Laboratories, Inc., Lakewood, New Jersey
Recalled by: Travenol Laboratories, Inc., Flint Division, Deerfield, Illinois, by letter, December 13, 1982. Firm initiated recall
Distribution: Nationwide and Singapore
Size & Quantity: Firm estimates 30,000 jars remain on market
Reason: The cream may be minimally superpotent.

Product: Arizona Fire Salt Free Relish in 7 ounce jars, Recall #F-116-3
Code: None
Manufacturer: Sugar's Kitchen, Tucson, Arizona
Recalled by: Manufacturer, by telephone, September 22, 1982. Firm initiated recall
Distribution: Alabama, Arizona, California, Florida, Illinois, Nevada, New Mexico, Texas
Size & Quantity: Firm estimates 20 cases remain on market
Reason: Jalapenos from swollen cans used as raw material.

Seizure Actions Filed:

Product: Special Legume Concentrate, also known as Phaseolamin, 500 mg., starch blocker tablets (82-247-501)
Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption
Firm: Paragon Laboratories, Torrance, California
Filed: December 9, 1982 - U.S. District Court for the District of Nevada at Las Vegas; Civil #CV LV '82-814 HEC, FDC #63795.

Product: Nutri-Sun Special Legume Concentrate Starch Blocker 750 mg. (83-247-527)
Charge: Product is a new drug marketed without an approved New Drug Application or notice of claimed investigational exemption
Firm: Paragon Laboratories, Torrance, California
Filed: December 9, 1982 - U.S. District Court for the District of Nevada at Las Vegas; Civil #CV LV '82-815 HEC, FDC #63893.

Product: "Sans Soleil Tanning Tablets and Vitamin A Supplement for Adults" (82-345-873)

Charge: Products are not hair dyes and they contain color additives, beta-carotene and canthaxanthin, which are unsafe within the meaning of the law because there is no regulation in effect that list this use of these color additives

Firm: P & B Enterprises, San Jose, California

Filed: December 13, 1982 - U.S. District Court for the Northern District of California at San Francisco; Civil #C-082-67316 WHO, FDC #63865.

Disposition of Prosecutions:

Defendants: Kings Trading, Inc., Kansas City, Missouri and Jar-Yu King, President

Nature of Charges: Holding food in a warehouse under insanitary conditions

Disposition: Defendants were convicted of two counts of violating the adulteration provisions of the statute. Mr. King was sentenced to one year in prison plus three years probation and the corporation was fined $20,000 plus four years probation. U.S. District Court for the Western District of Missouri

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Defendants: Garson, Borstein, and Nichta, Bedford Heights, Ohio

Nature of Charges: Storing food under insanitary conditions whereby they may have become contaminated with filth

Disposition: Defendants pleaded guilty to four counts of violating the adulteration provisions of the statute. Each defendant was sentenced to five years probation and ordered to pay a total of $4,000 in fines. In addition, the Court ordered semi-annual FDA inspections of the defendants' food storage and distribution facility. U.S. District Court for the Northern District of Ohio.

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